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(54) **MEDICAL DEVICE CONTROL SYSTEM**

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Related U.S. Application Data

(63) Continuation-in-part of application No. 11/165,593, filed on Jun. 22, 2005, now Pat. No. 7,618,413.

(51) **Int. Cl.**
A61B 17/00 (2006.01)

(52) **U.S. Cl.** **606/1**; 600/146

(58) **Field of Classification Search** 600/101, 600/104, 117, 118, 121, 131, 146, 148, 149; 604/95.04; 606/1

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,254,088	A *	10/1993	Lundquist et al.	604/95.04
5,284,130	A *	2/1994	Ratliff	600/229
5,325,845	A *	7/1994	Adair	600/114
6,013,024	A *	1/2000	Mitsuda et al.	600/146
6,033,378	A *	3/2000	Lundquist et al.	604/95.01
6,551,237	B2 *	4/2003	Matsui	600/118
6,793,622	B2 *	9/2004	Konomura et al.	600/152
7,338,505	B2 *	3/2008	Belson	606/150
7,410,483	B2 *	8/2008	Danitz et al.	606/1
7,608,083	B2 *	10/2009	Lee et al.	606/130
2002/0165430	A1 *	11/2002	Matsui	600/118
2003/0018237	A1 *	1/2003	Okada	600/146
2003/0050649	A1 *	3/2003	Brock et al.	606/130
2003/0092965	A1 *	5/2003	Konomura et al.	600/146
2003/0135204	A1 *	7/2003	Lee et al.	606/1
2004/0059191	A1 *	3/2004	Krupa et al.	600/146
2004/0181140	A1 *	9/2004	Falwell et al.	600/374
2004/0193016	A1 *	9/2004	Root et al.	600/146
2004/0236316	A1	11/2004	Danitz et al.	
2004/0267093	A1 *	12/2004	Miyagi et al.	600/146
2005/0075538	A1 *	4/2005	Banik et al.	600/141
2005/0096694	A1	5/2005	Lee	
2005/0154261	A1 *	7/2005	Ohline et al.	600/141
2005/0245789	A1 *	11/2005	Smith et al.	600/159
2006/0007184	A1 *	1/2006	Rosenberg et al.	345/173

FOREIGN PATENT DOCUMENTS

WO	WO 94/21179 A2	9/1994
WO	WO 97/12557 A1	4/1997

* cited by examiner

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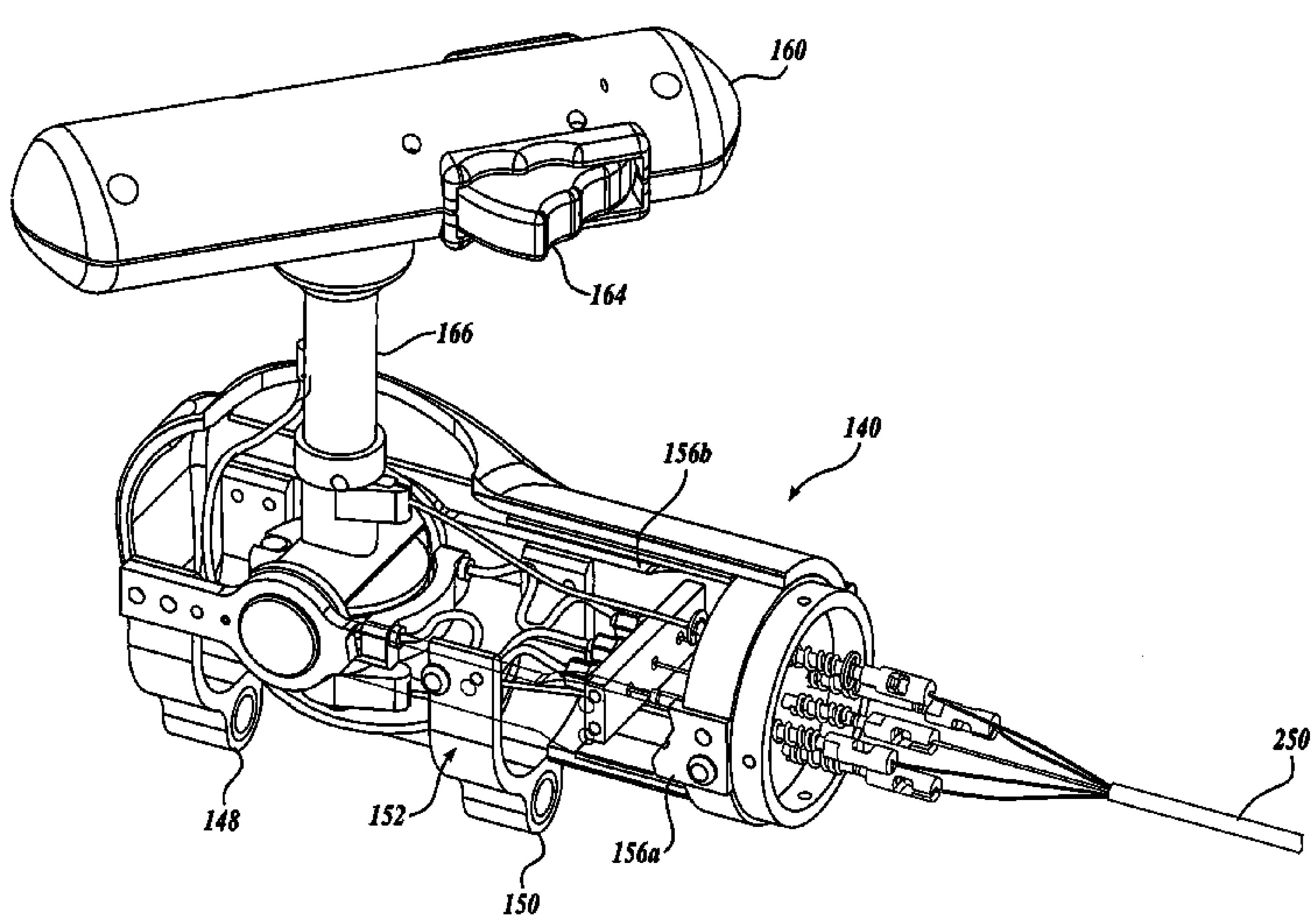
(57) **ABSTRACT**

A control system for allowing a user to control the orientation of a medical device or a medical instrument in a variety of directions. An actuator selectively tensions one or more control cables having ends secured at or adjacent a distal tip of the medical device in order to bend the distal tip in a desired direction. In one embodiment, a physician can adjust the movement of the distal tip in a desired direction without affecting the orientation of the medical device in other directions.

20 Claims, 17 Drawing Sheets



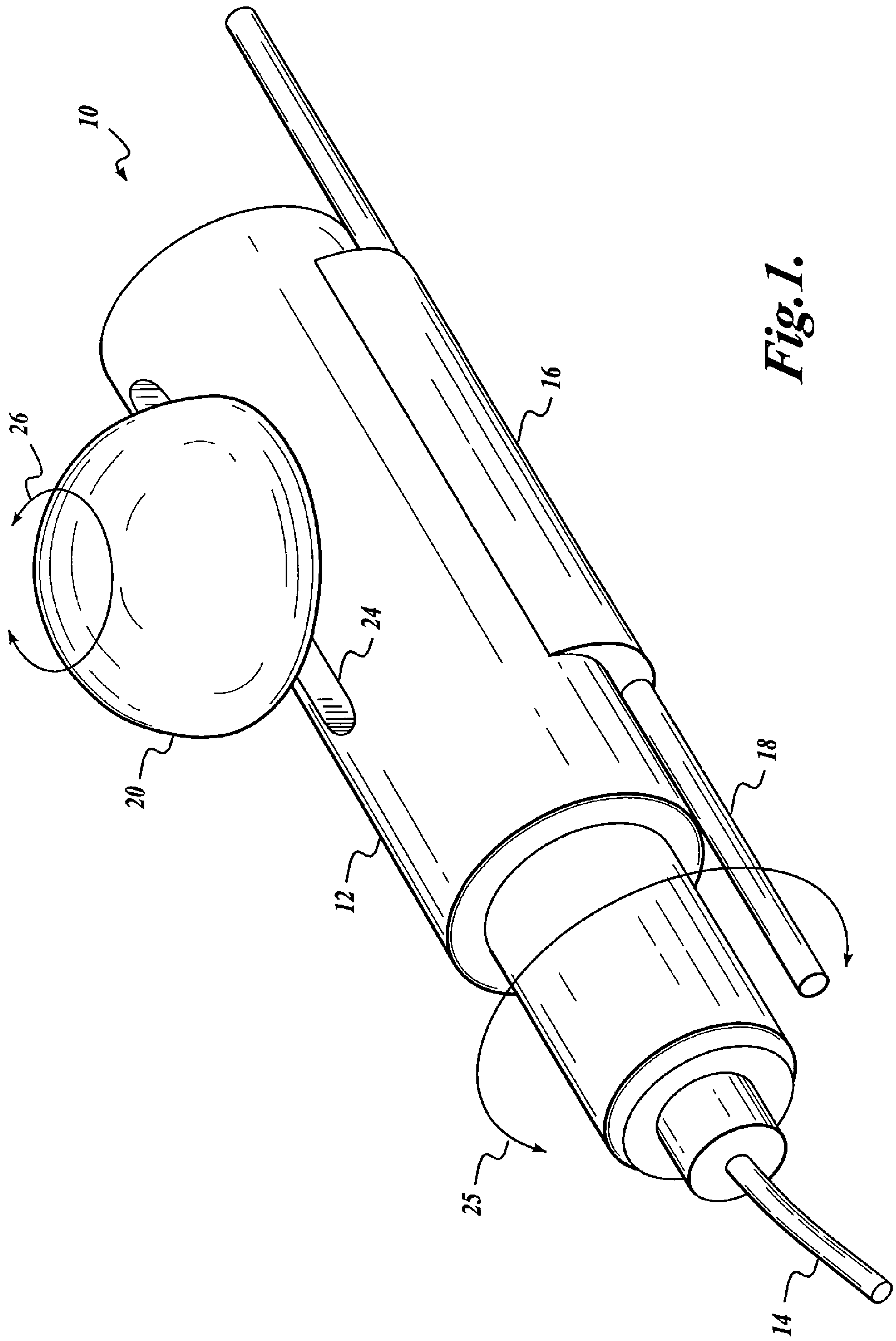


Fig.1.

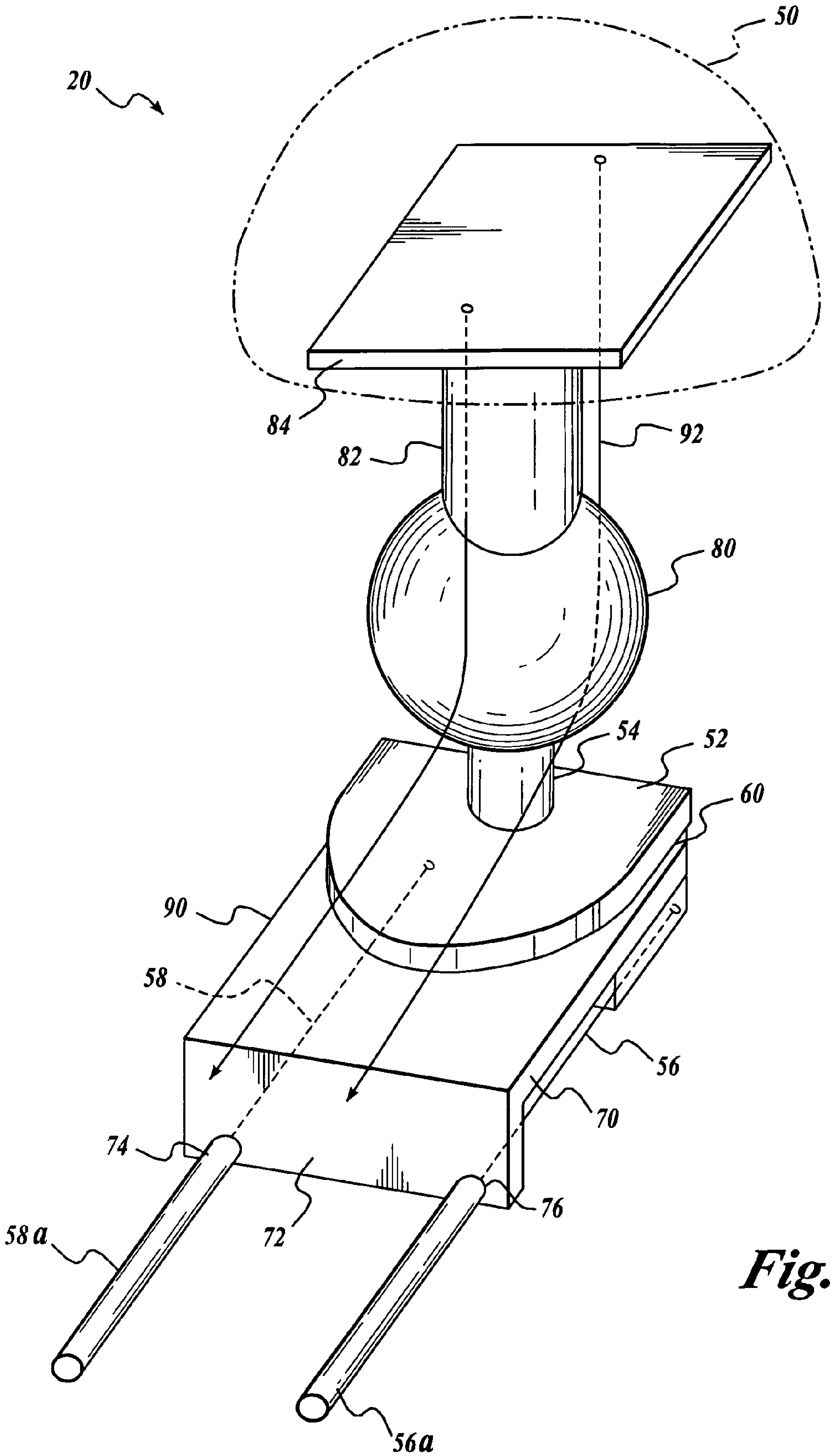


Fig.2.

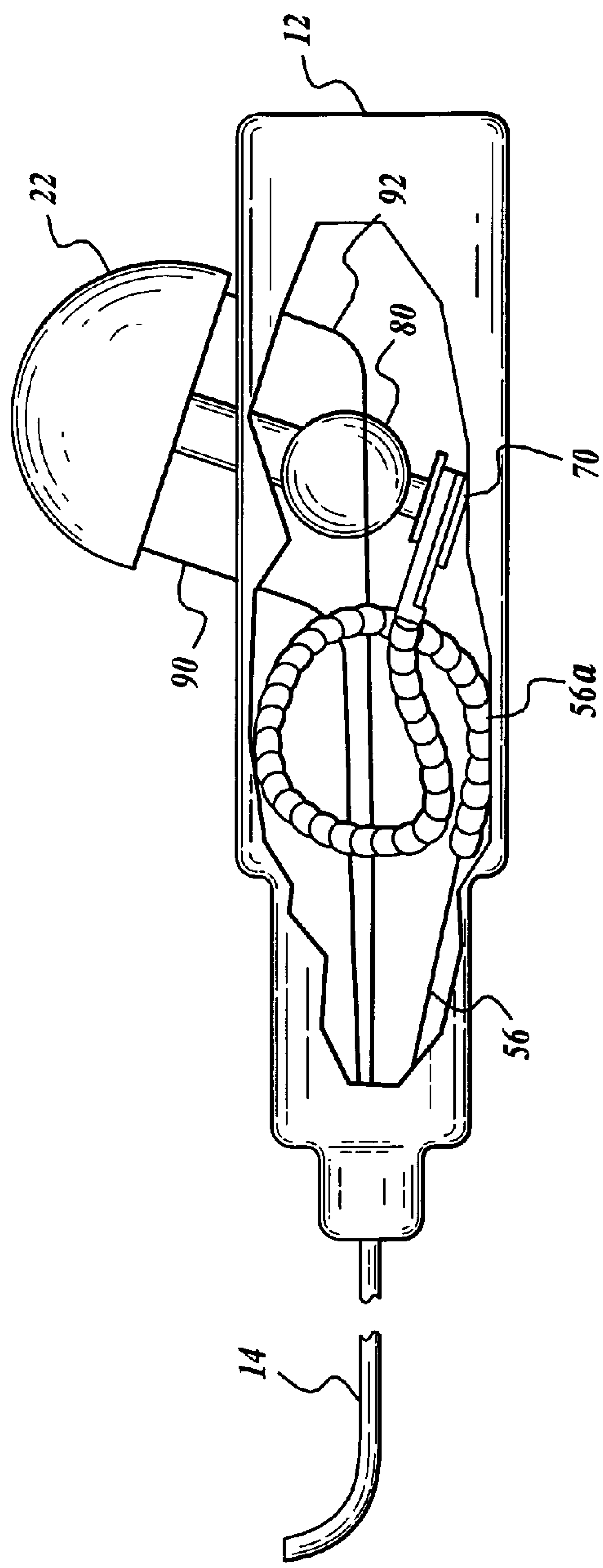


Fig.3A.

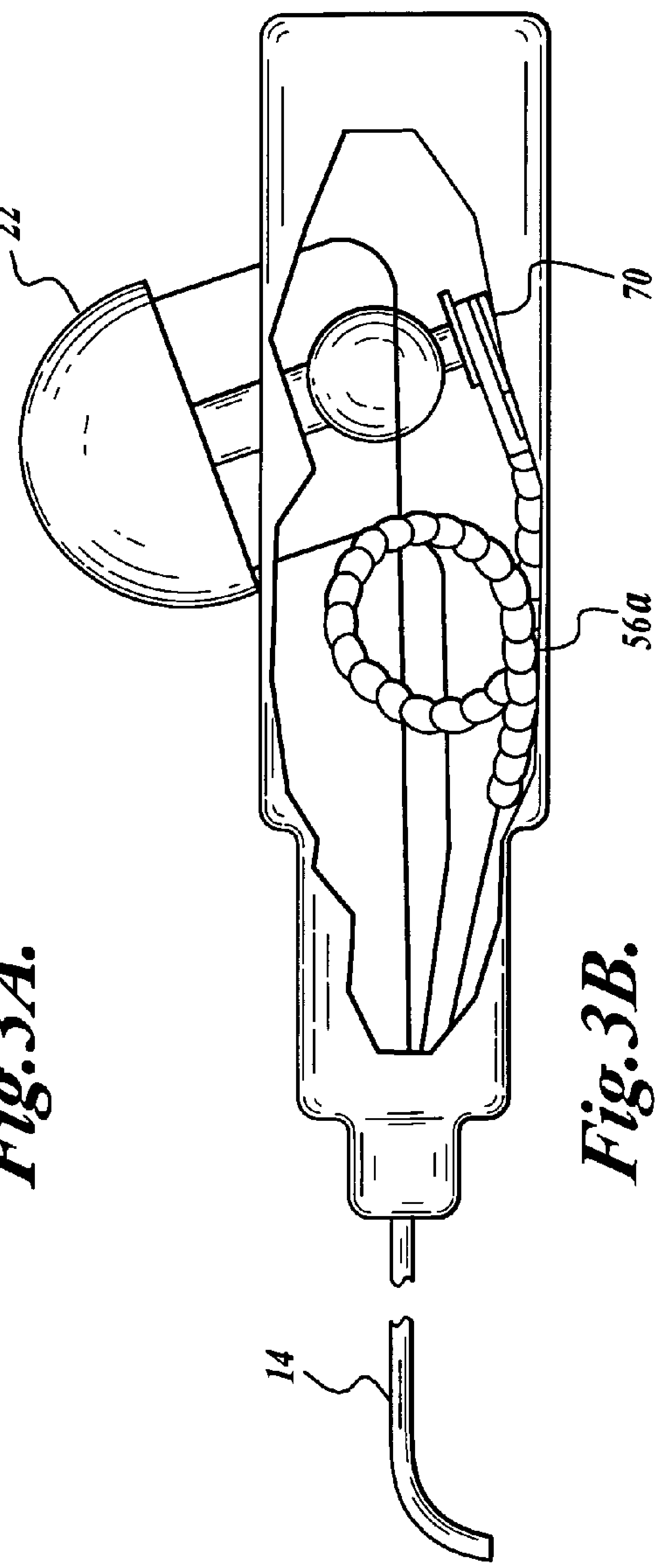


Fig.3B.

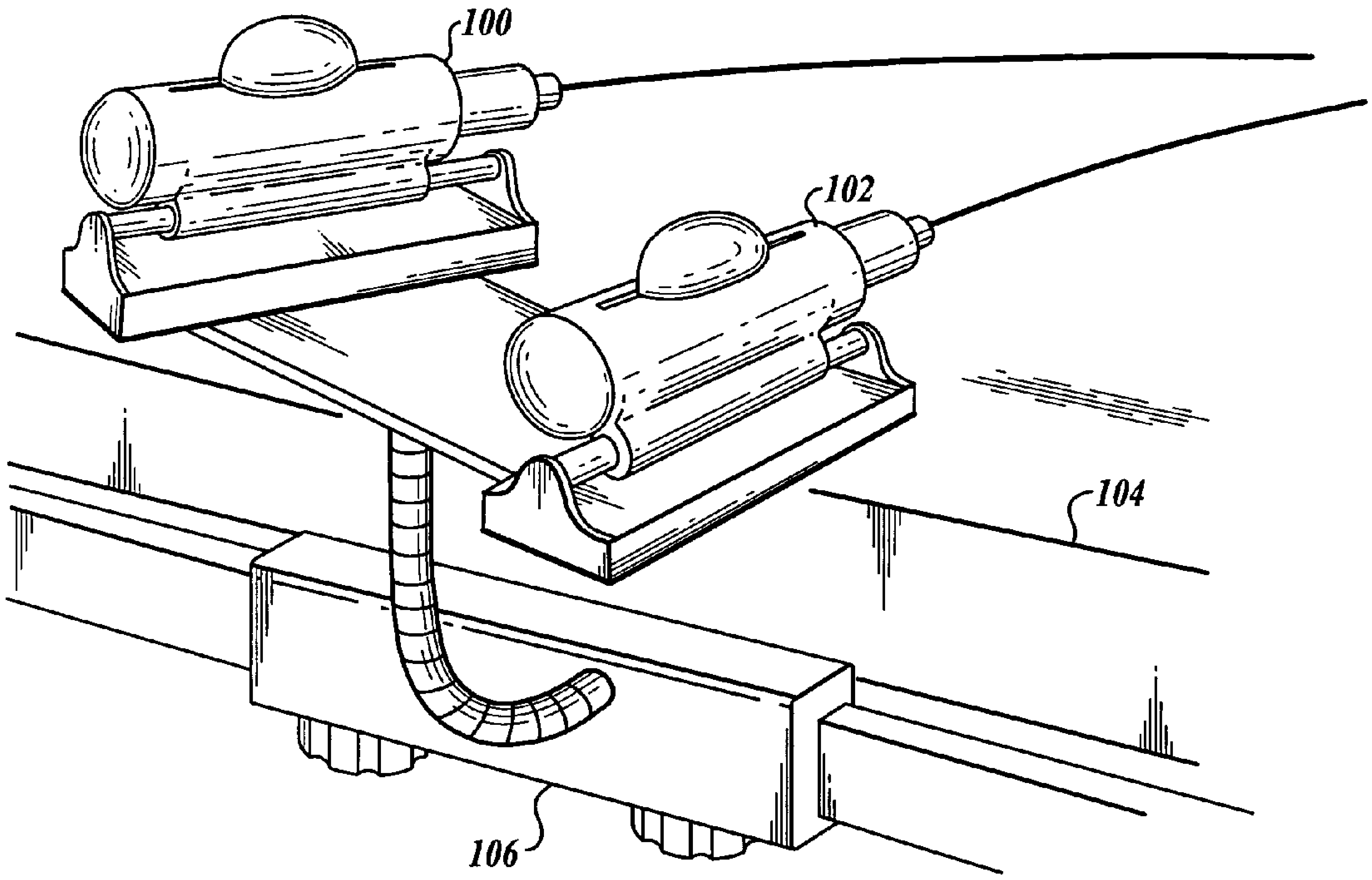


Fig.4.

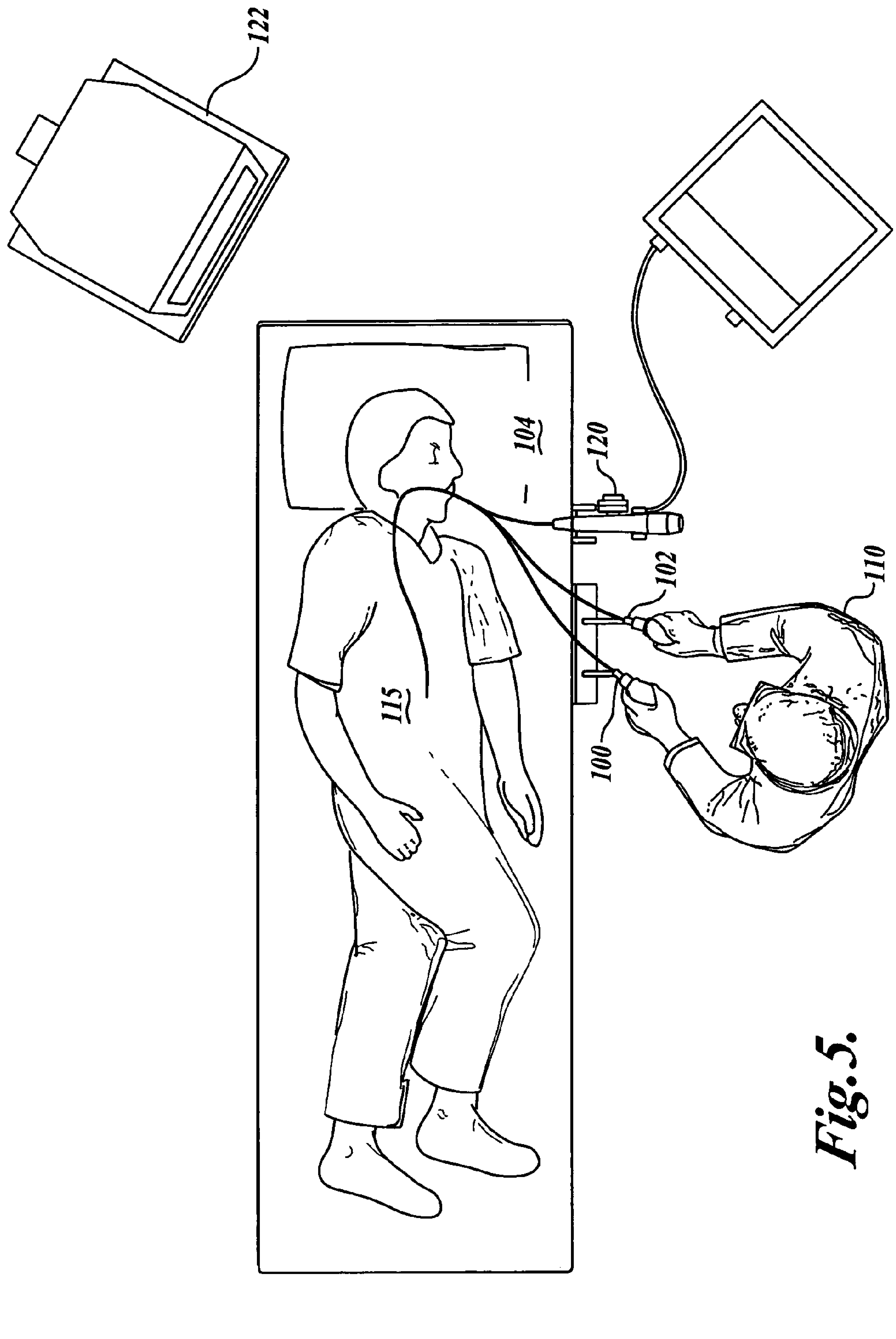


Fig.5.

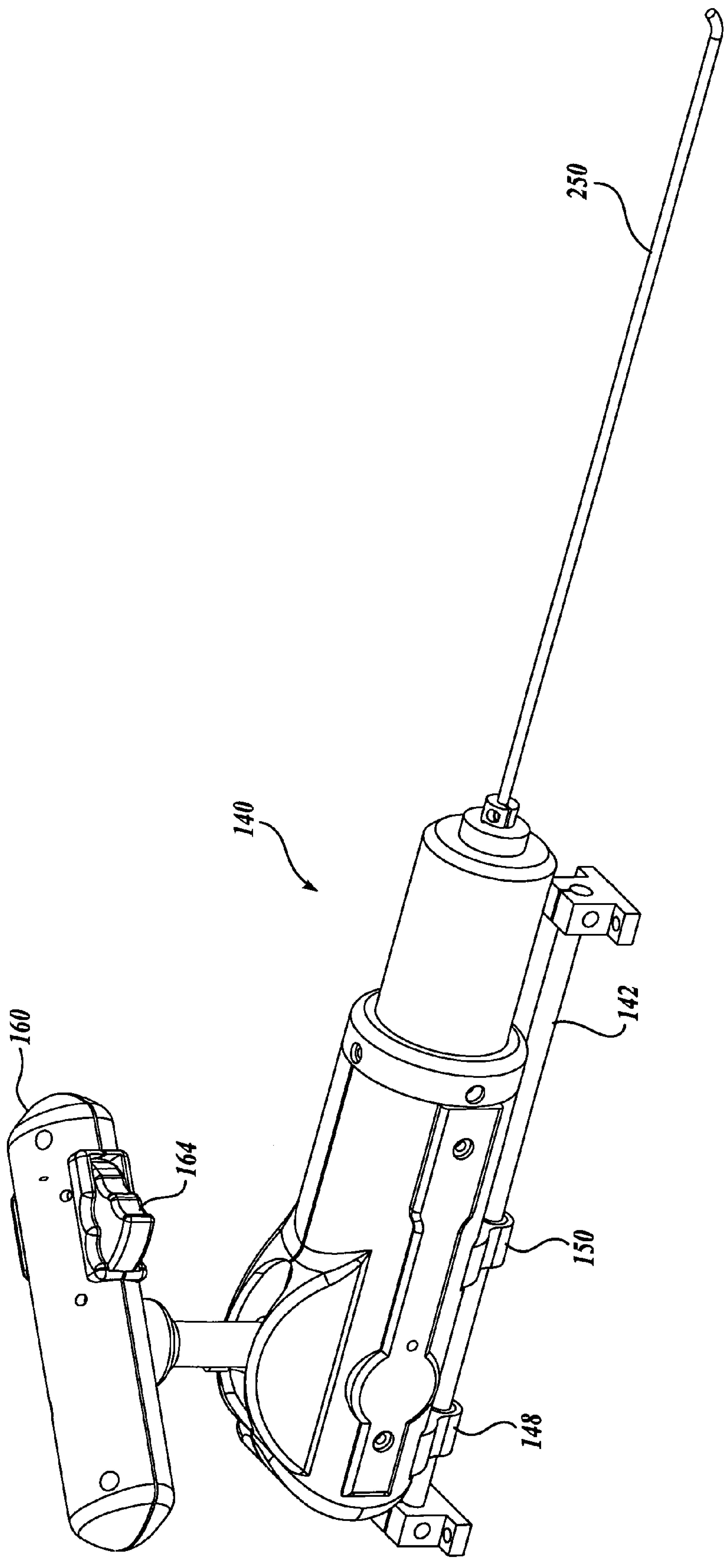
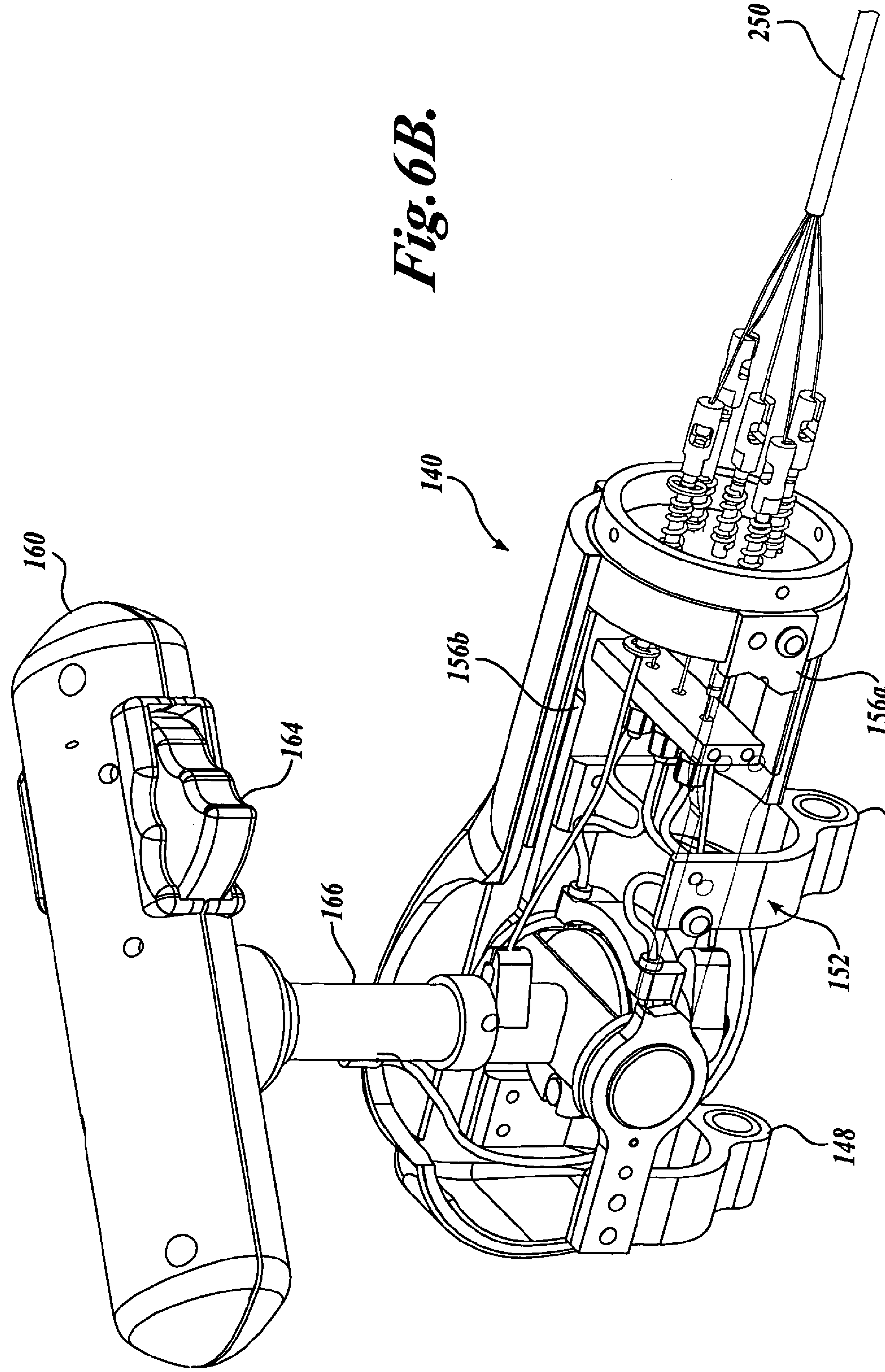


Fig. 6A.

Fig.6B.



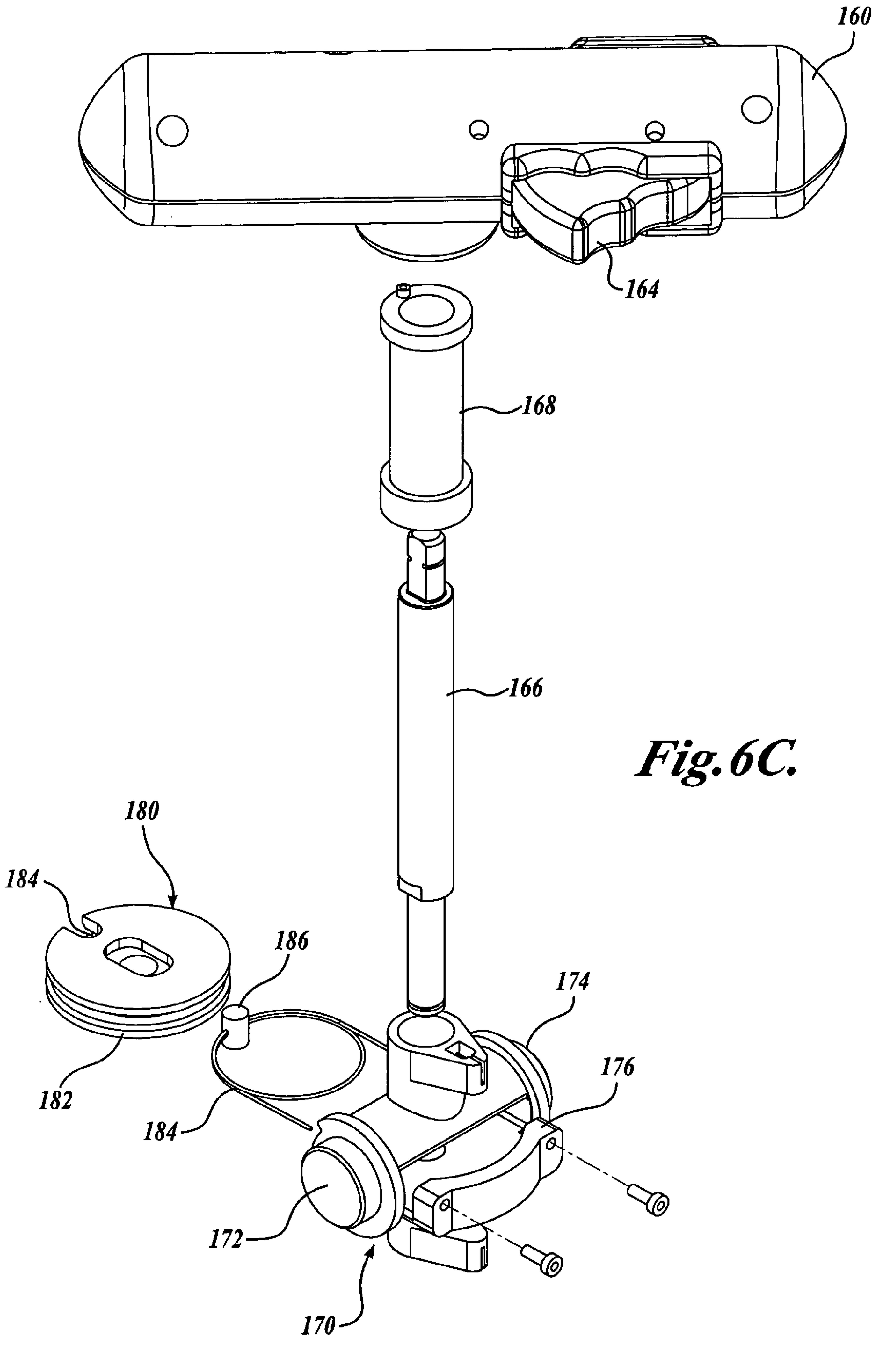
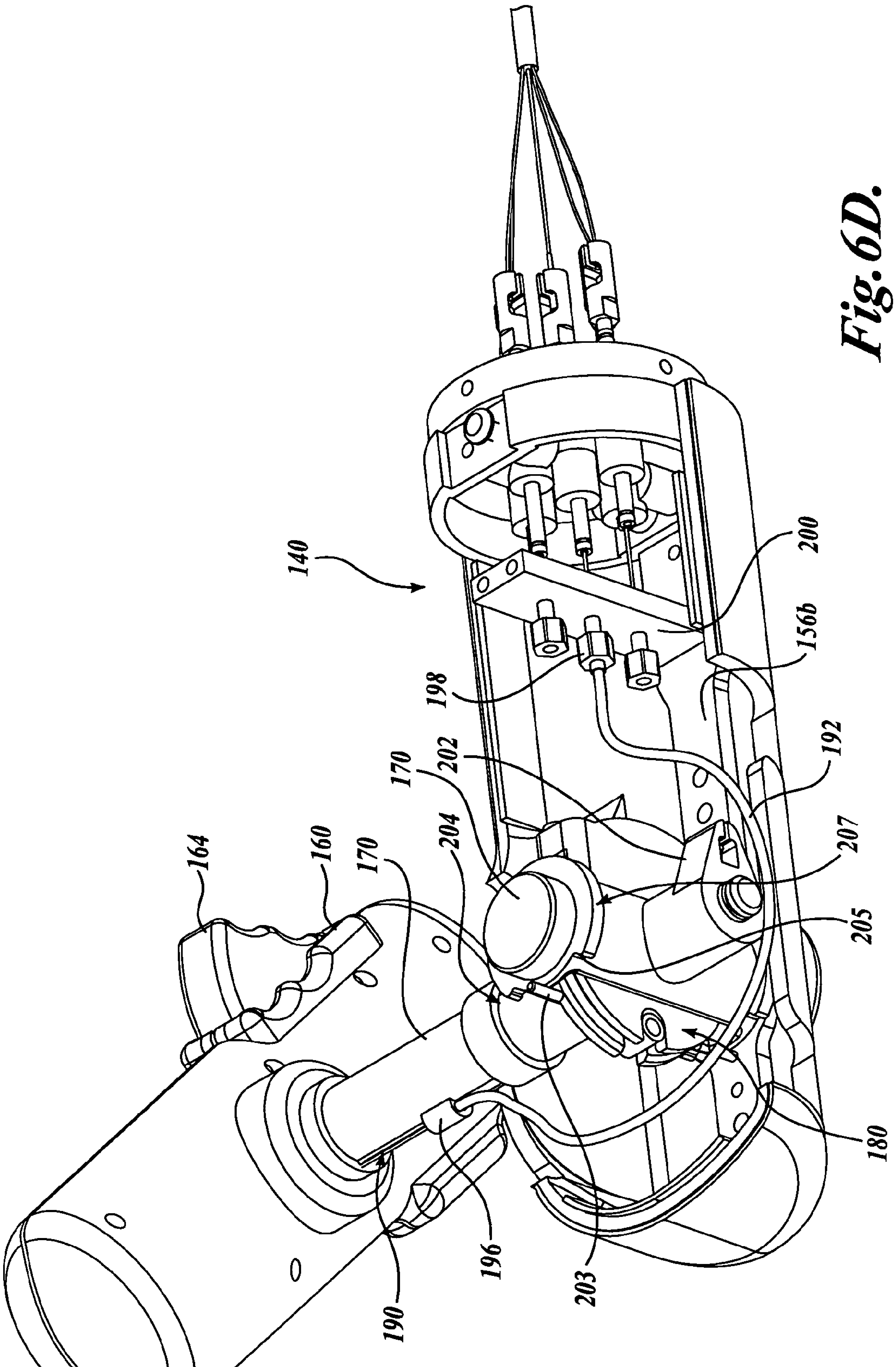


Fig.6C.


140
200
156b
198
170
202
192
164
160
170
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207
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203

Fig.6D.

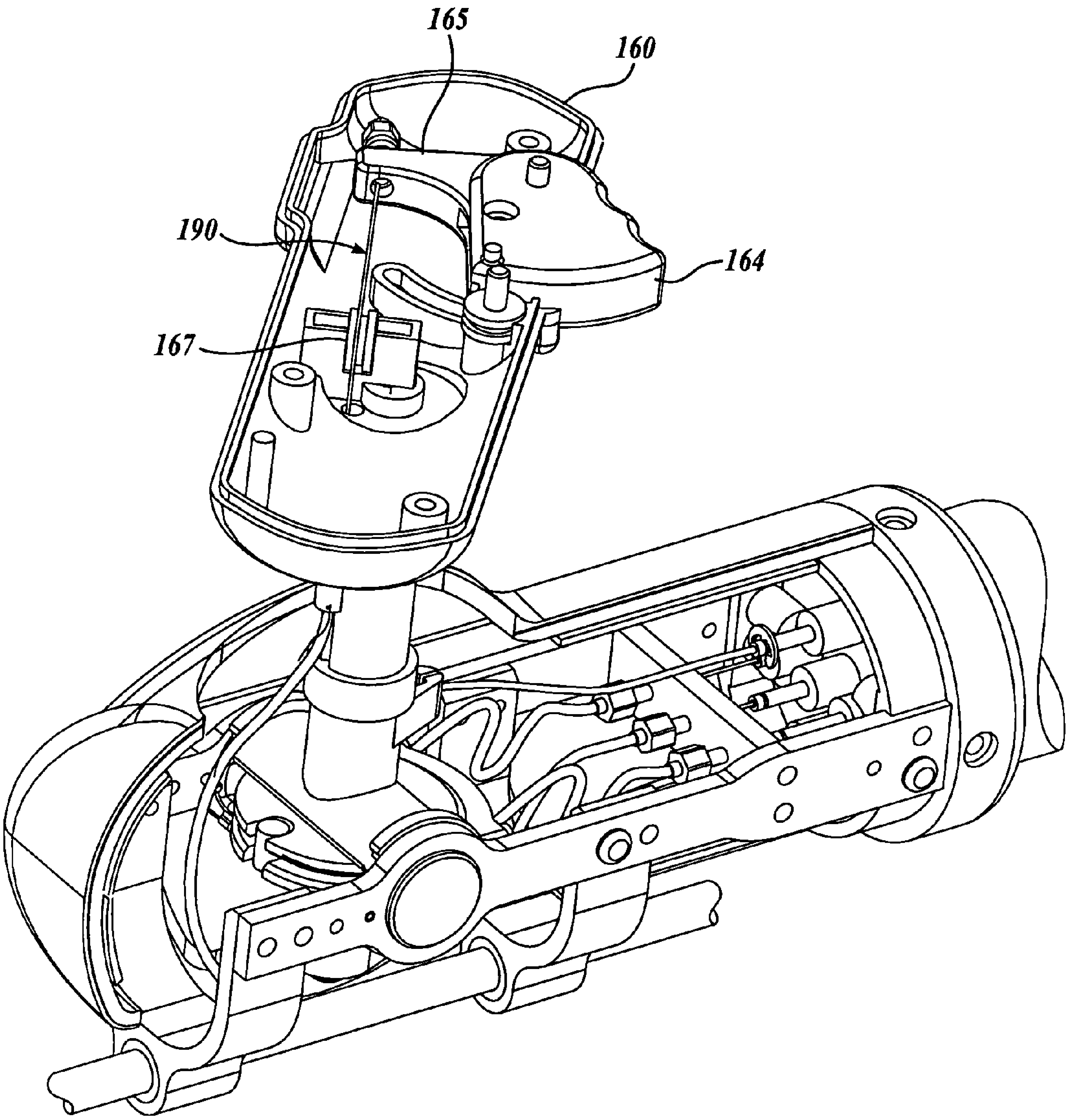

Fig.6E.

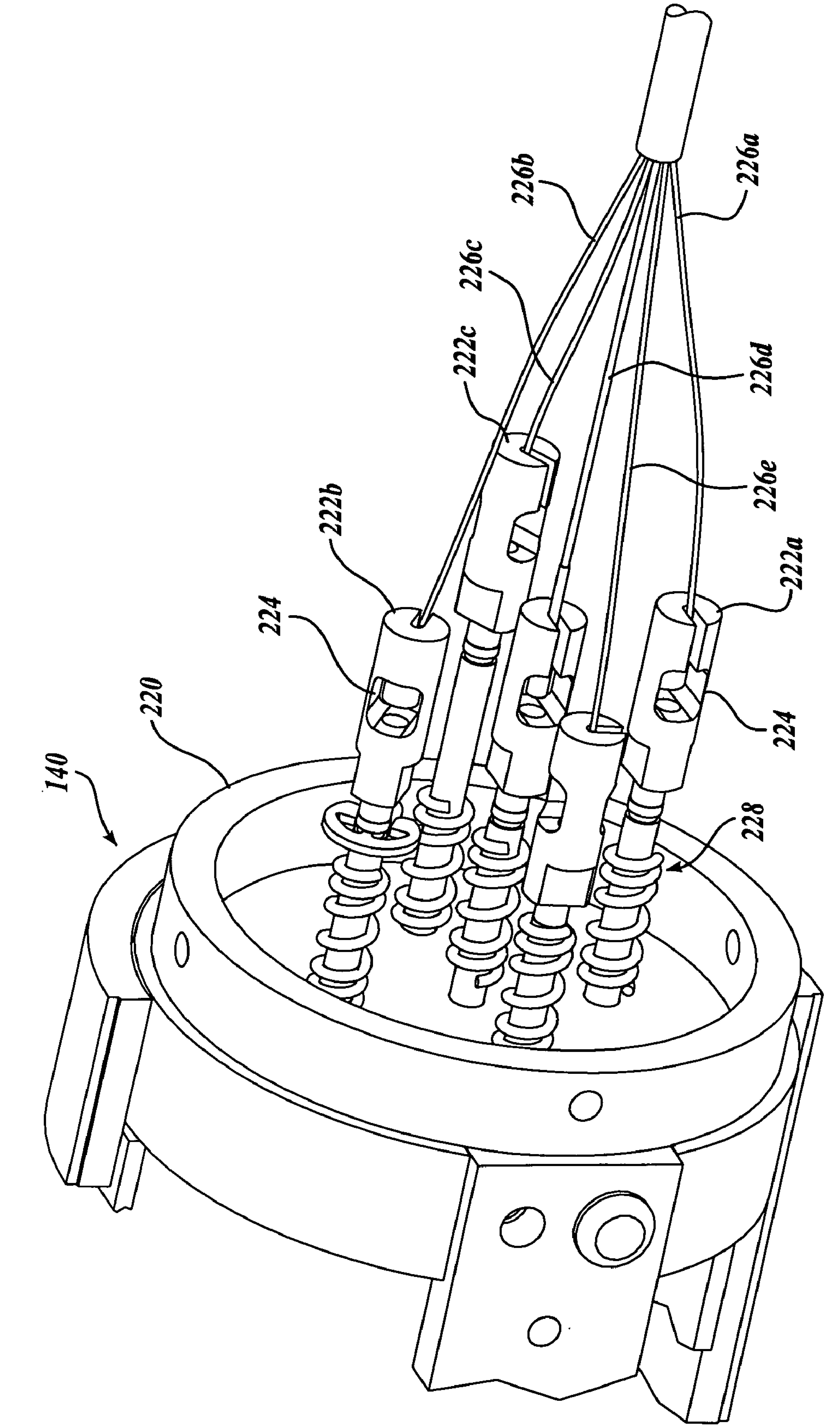

Fig.6F.

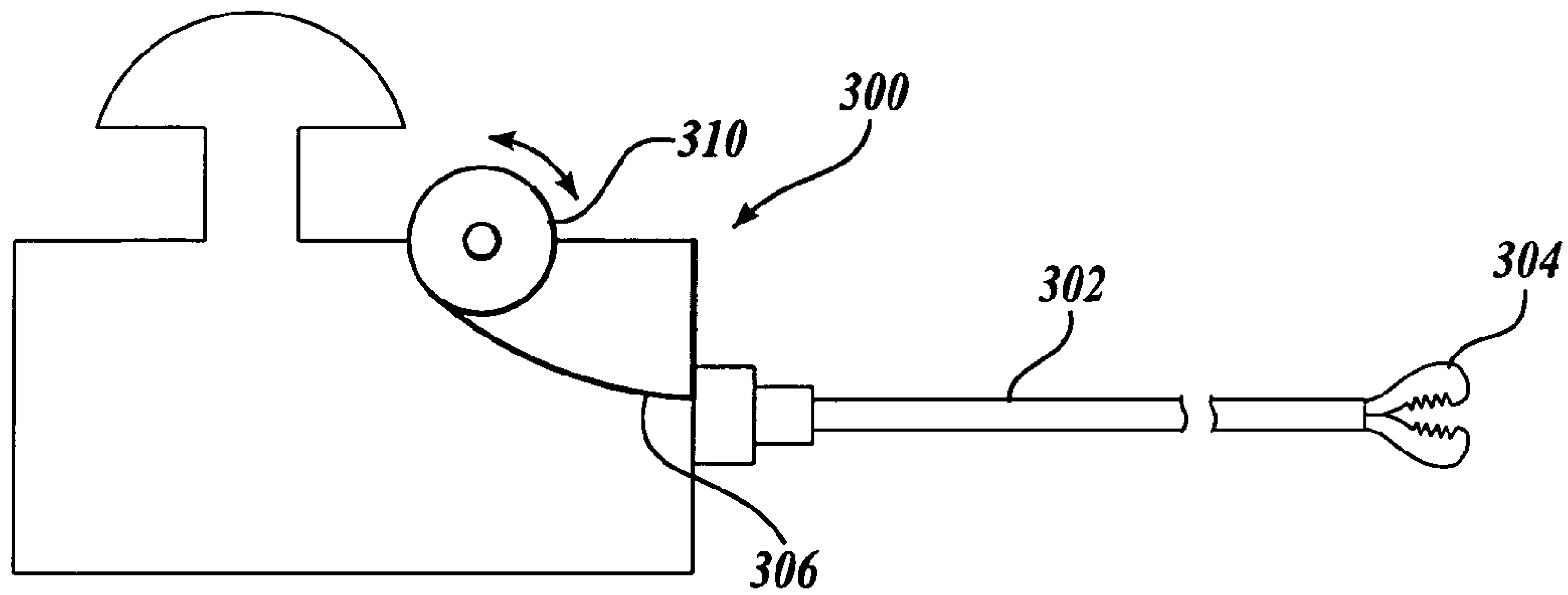

Fig. 7A.

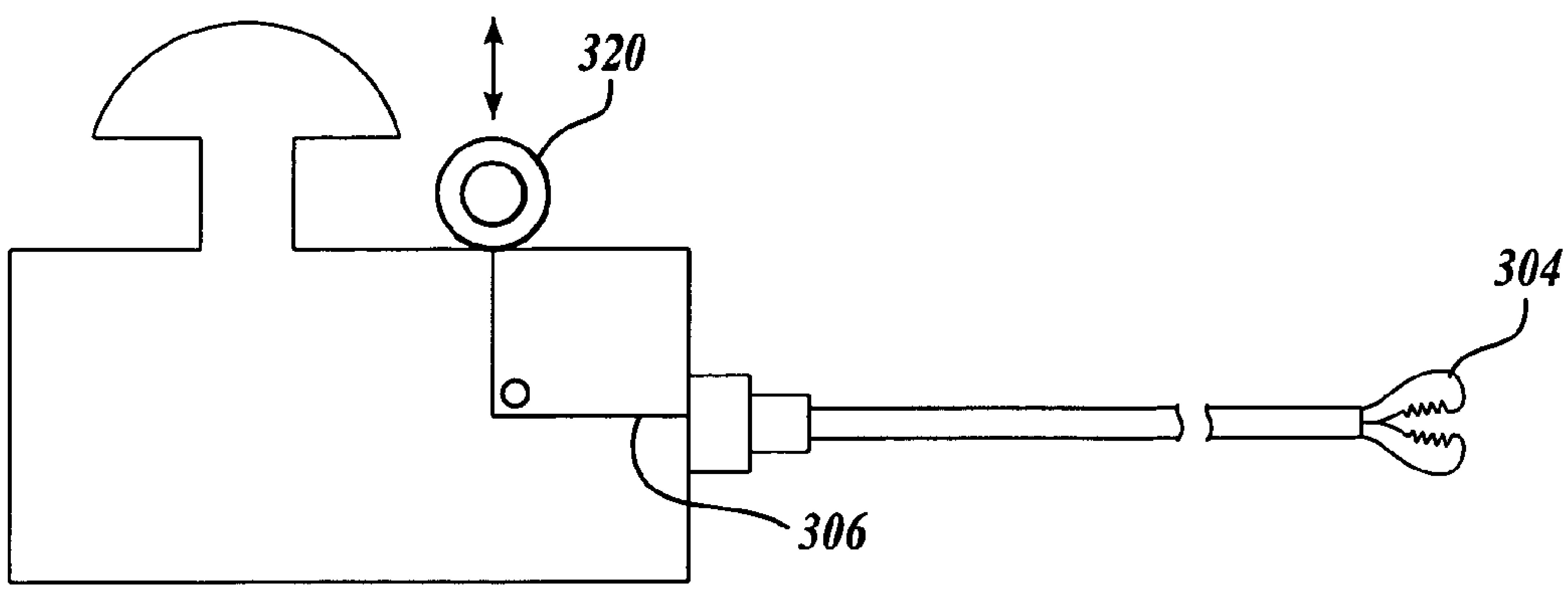

Fig. 7B.

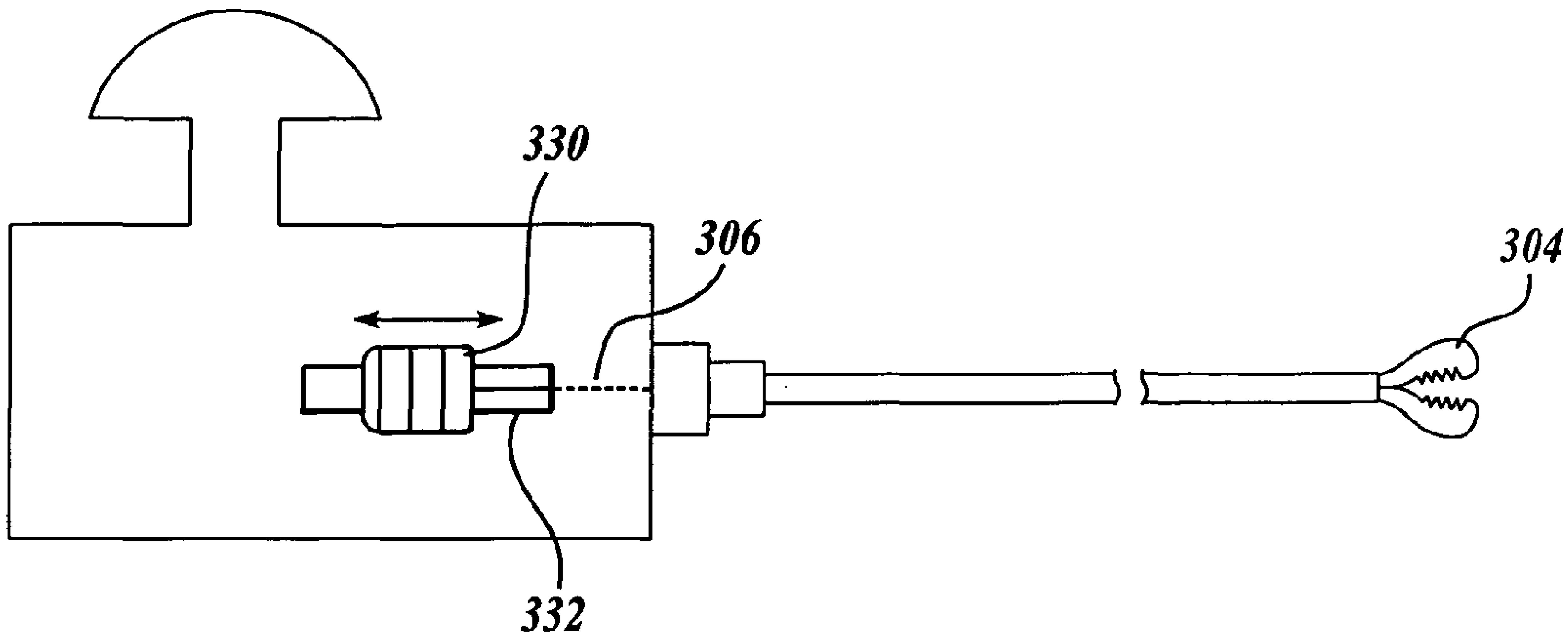

Fig. 7C.

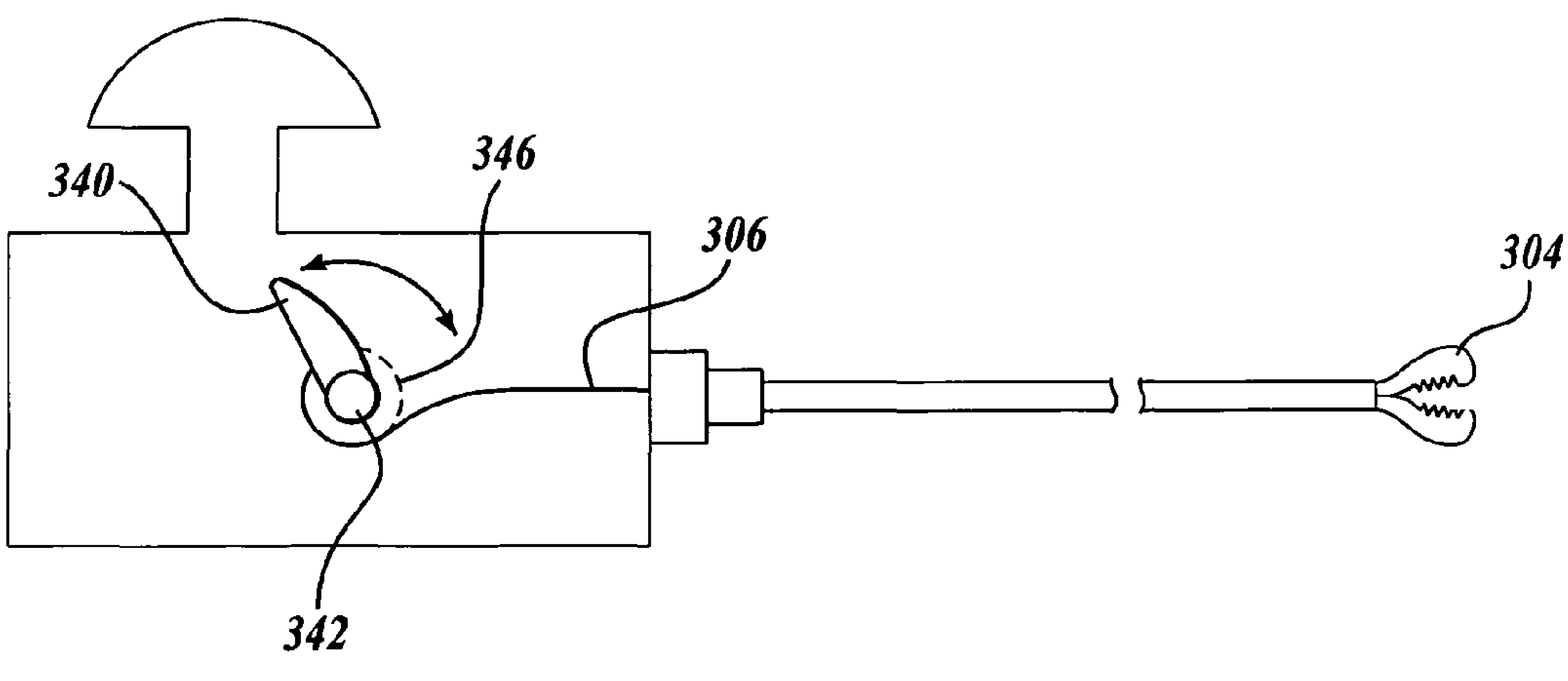

Fig. 7D.

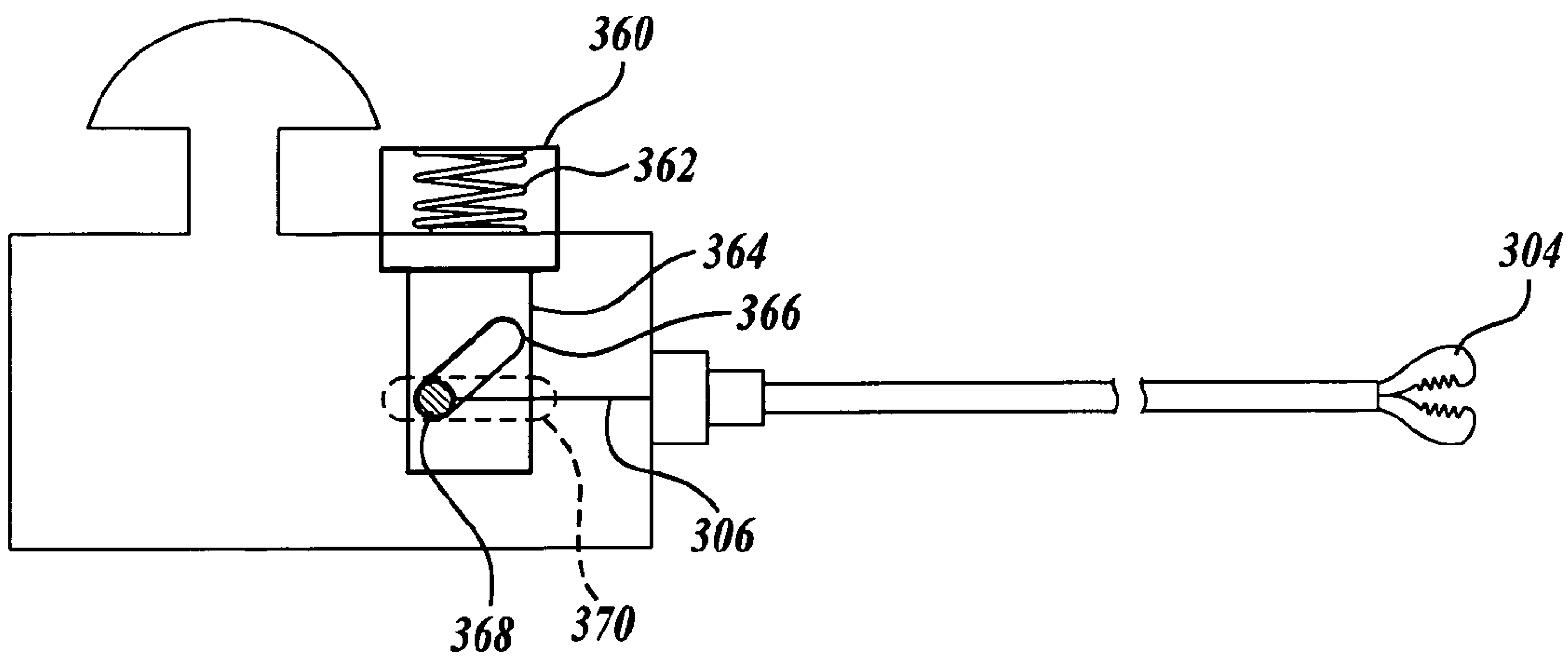

Fig. 7E.

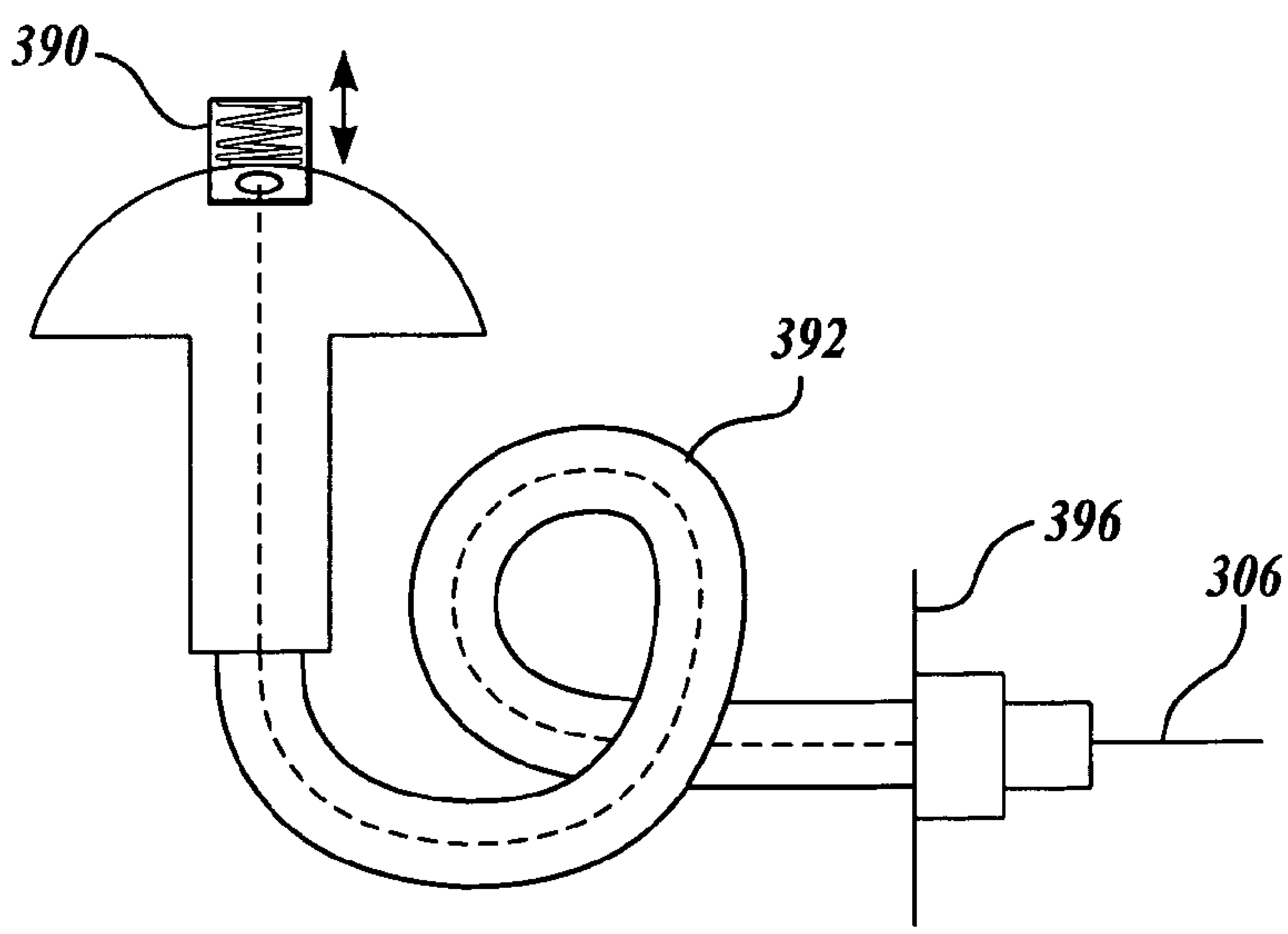

Fig. 7F.

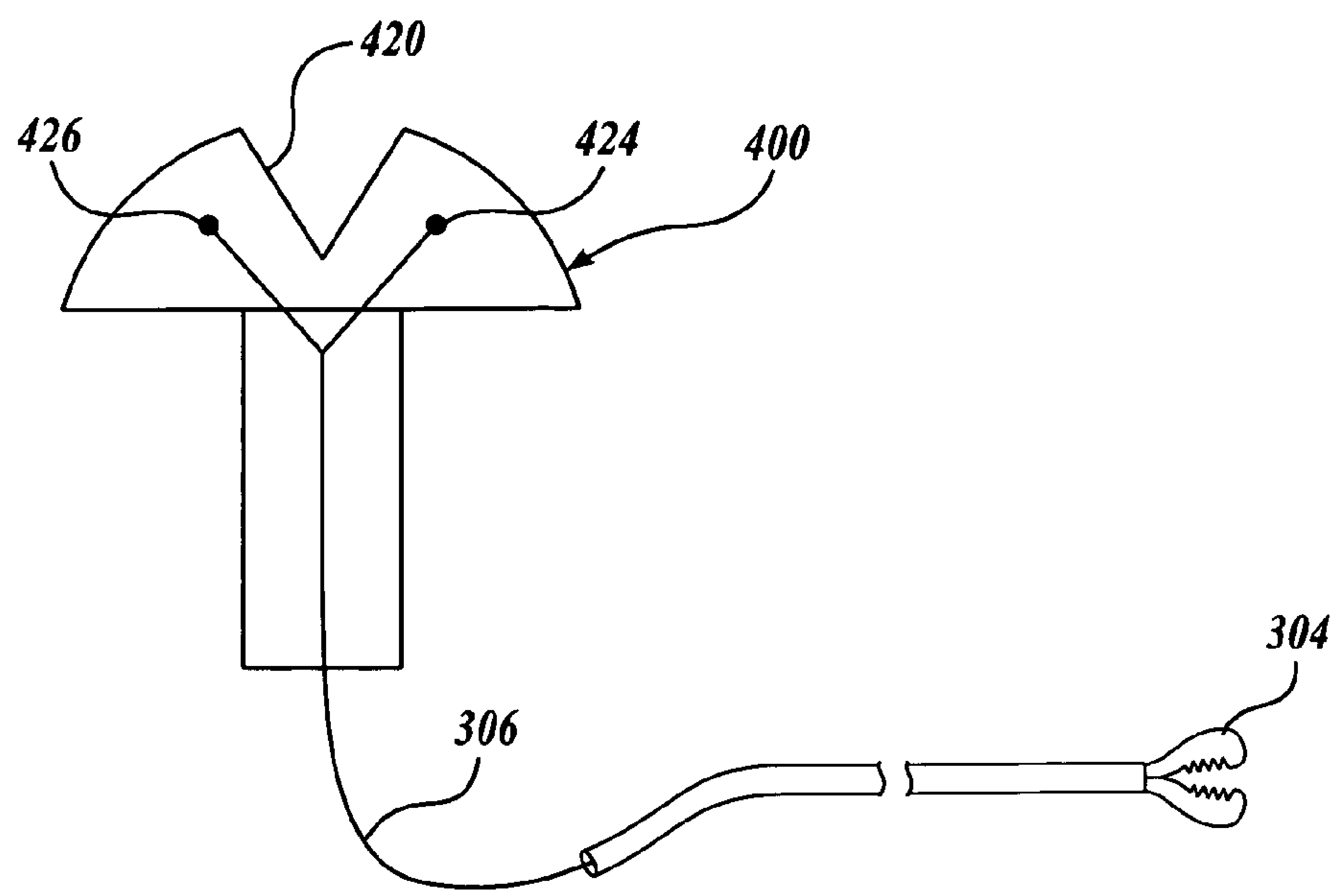

Fig. 7G.

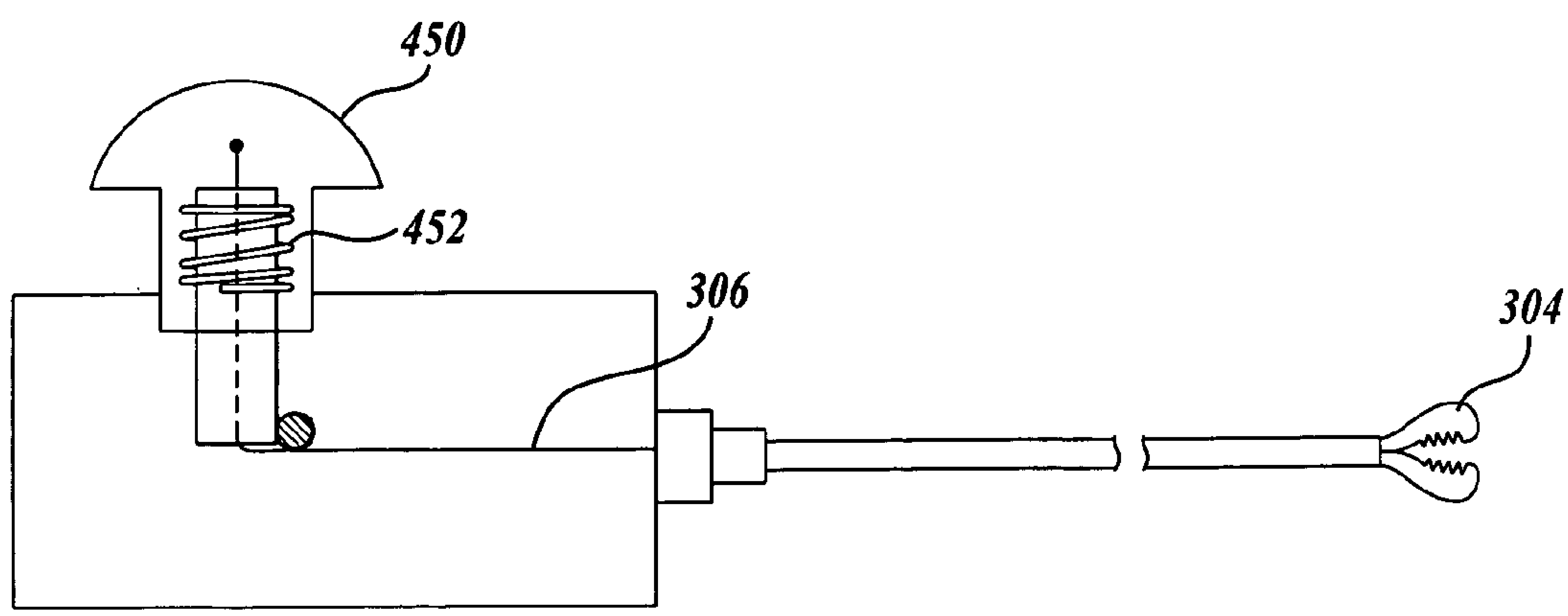

Fig. 7H.

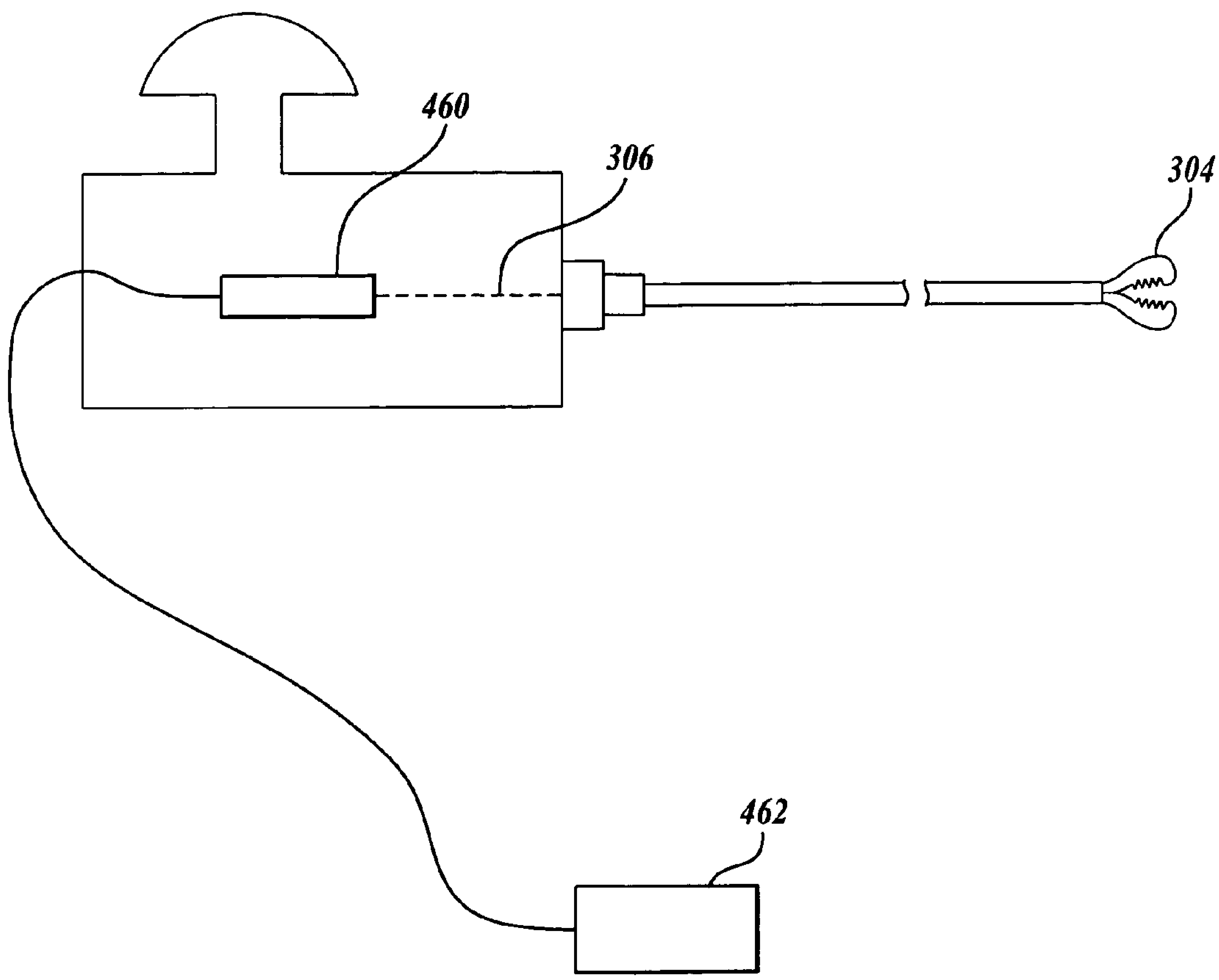

Fig. 7I.

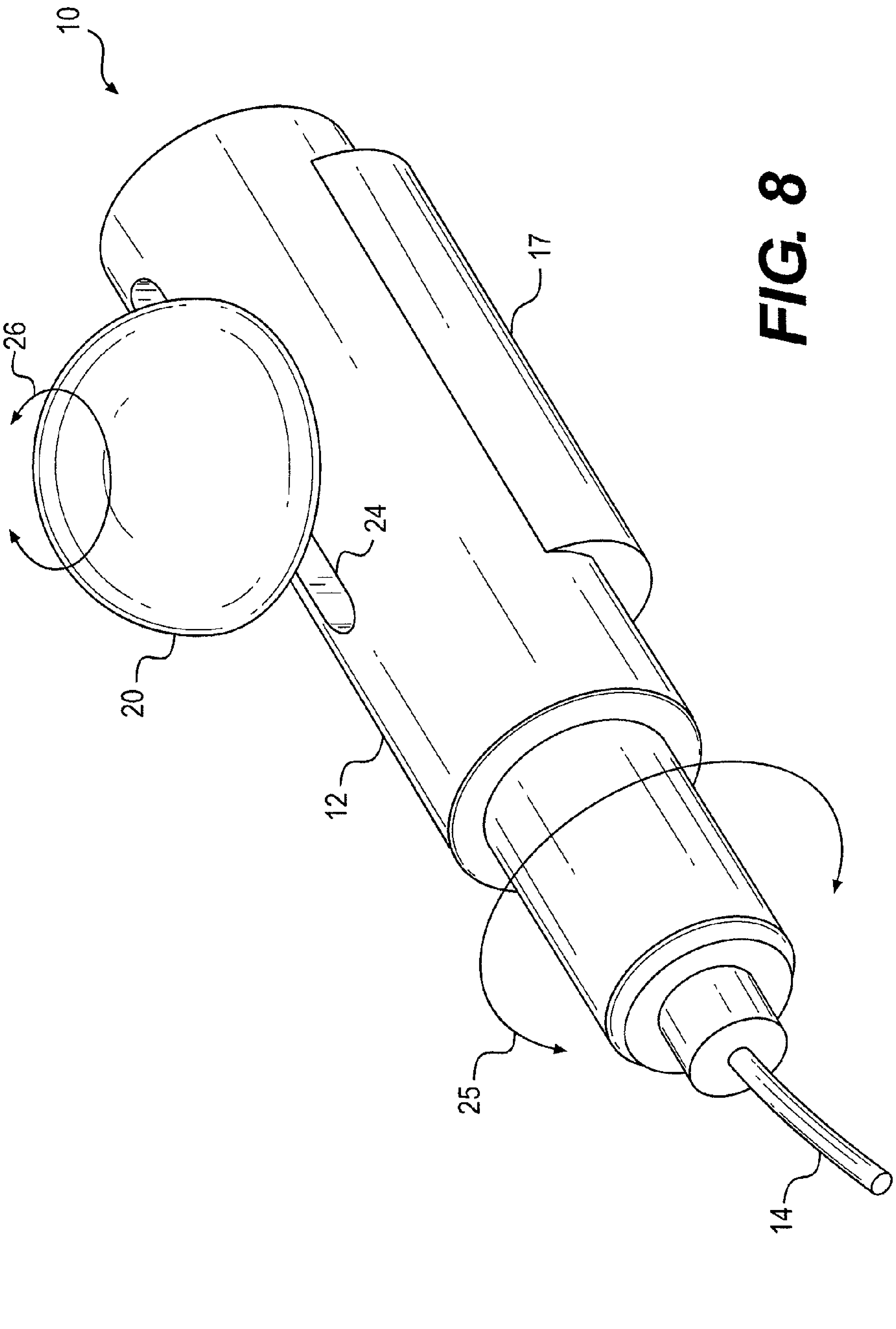

FIG. 8

MEDICAL DEVICE CONTROL SYSTEM

CROSS-REFERENCE TO RELATED APPLICATION

The present application is a continuation-in-part of U.S. patent application Ser. No. 11/165,593, filed Jun. 22, 2005, which has issued as U.S. Pat. No. 7,618,413, the benefit of which is hereby claimed under 35 U.S.C. §120 and is fully incorporated by reference.

BACKGROUND

The present invention relates to medical devices in general and, in particular, to devices for manipulating steerable medical devices or other minimally invasive tools within a patient's body.

Steerable medical devices and other minimally invasive surgical tools are being increasingly used to perform medical procedures inside a patient's body. Steerable devices generally include an elongated shaft and one or more control cables having distal ends secured at or adjacent the distal tip of the shaft. A control knob or lever selectively tightens the control cables in order to bend the device in a desired direction. The problem with most medical device controllers is that they require two hands in order to move the distal tip of a device in more than one plane. Alternatively, in those designs where a user can move the distal tip in four directions with one hand, two hands are still required in order to advance, retract, or rotate the device. Although some robotic systems have been proposed to allow a physician to direct a distal tip of a device in any direction using motors, these systems are generally expensive and complicated.

SUMMARY

The present invention is a control system for selectively orienting the distal tip of a steerable medical device. In one embodiment, the control has a body with an actuator that can be independently moved in at least two directions so movement of the actuator in each direction moves the distal tip of the medical device in a plane. In one embodiment, the control may be mounted on a rail that is fixed with respect to the location of a patient such that advancement or retraction or rotation of the actuator body on the rail causes a corresponding advancement, retraction, or rotation of the medical device. In one particular embodiment, the actuator allows movement of the distal tip in one plane to be decoupled from movement in another plane.

This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This summary is not intended to identify key features of the claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter.

DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIG. **1** is an elevated isometric view of a medical device control system in accordance with one embodiment of the present invention;

FIG. **2** illustrates one embodiment of an actuator for moving a medical device in accordance with the present invention;

FIGS. **3**A and **3**B illustrate how an embodiment of the invention isolates movement of the distal tip of a controlled medical device;

FIG. **4** illustrates how two control systems can be used by a physician;

FIG. **5** illustrates how a physician operates a control system with each hand;

FIGS. **6**A-**6**F illustrate another embodiment of a control system for moving a medical device in accordance with the present invention;

FIGS. **7**A-**7**I illustrate a number of alternative trigger mechanisms for actuating a tool in accordance with embodiments of the present invention; and

FIG. **8** is an elevated isometric view of a medical device control system in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION

As indicated above, the present invention is a control system for selectively orienting a steerable medical device in a number of directions. In one embodiment of the invention, the control **10** includes a ergonomic, generally cylindrical body **12** having an actuator (described below) that operates to selectively tighten or release control cables that cause the distal tip of a medical device **14** such as a catheter, visualization device or instrument to bend in a desired direction. The control body **12** includes one or more clamps **16** that allow it to be moved along a length of a rail **18** in order to advance or retract the medical device **14** as well as to provide rotation of the medical device around its longitudinal axis. The clamps **16** may provide a friction force that is overcome by a user in order to move the control body **12** along the rail **18**. Alternatively, the clamps **16** may include release mechanisms such as a brake or lock that should be loosened to adjust the position of the control body **12** with respect to the rail **18**. In yet another embodiment, the clamps **16** and rail **18** may include a gear to move the control body **12**. The rail **18** may be clamped to a patient table or otherwise remain fixed with respect to the location of the patient such that the position of the medical device **14** remains constant if the physician's hand is removed from the control **10**.

The control **10** can be rotated about the longitudinal axis of the rail **18** in the direction of the arrow **25** in order to impart rotational motion or torque to the medical device **14**. Although the center axis of the medical device **14** is offset from the central axis of the rail **18**, the medical device **14** is usually routed through a guiding device such as an endoscope or other constraining mechanism such that movement of the control **10** about the axis of the rail **18** causes the distal tip of the medical device **14** to rotate around the longitudinal axis of the device.

The control **10** also includes an actuator **20** that is used by a physician, or their assistant, in order to move the distal tip of the medical device **14** in one or more of the up/down or right/left directions. In one embodiment, the actuator **20** can be moved forward or backward within a slot **24** that extends longitudinally along the top of the body **12** in order to move the distal tip of the medical device **14** up or down. In addition, the actuator **20** can be rotated as indicated by the arrow **26** in order to move the distal tip of the medical device in the right/left directions. As will be explained in further detail below, movement of the distal tip in the up/down direction is decoupled from movement of the distal tip in the right/left direction so that a physician can maintain the orientation of the distal tip in the up/down direction while changing the right/left orientation or vice versa. Using the control **10**, the physician is able to adjust the orientation of the distal tip of the medical device with one hand.

As indicated above, this embodiment of the control **10** allows an operator to adjust the orientation of a medical device with four degrees of freedom (up/down, left/right, forward/backward and rotationally) using one hand. FIG. **2** illustrates one embodiment of an actuator **20** for allowing a physician to change the up/down and right/left orientation of a distal tip of a medical device. The actuator **20** has a cap **50** that is connected to a cable guide plate **52** through a shaft **54**. Rotation of the cap **50** about the longitudinal axis of the shaft **54** causes tension of one pair of control cables **56**, **58**. Tension of the control cable **56** causes a medical device tip to bend in the left direction, while tension on a control cable **58** causes a medical device tip to move in the rightward direction. The cable guide plate **52** is generally semi-circular in shape, with a rounded front end and a groove **60** therein to guide the corresponding control cables **56**, **58**. In the embodiment shown, the rear face of the cable guide plate **52** is generally flat. The ends of the control cables **56**, **58** may be either fixedly secured to the cable guide plate **52** or slidably secured to the guide plate. If fixedly secured to the cable guide plate **52**, then one control cable is tensioned while the other control cable is compressed as the cable guide plate **52** is rotated by the cap **50**. If the ends of the control cables are slidably secured to the cable guide plate **52**, then one control cable is tensioned and the other is released from tension as the cable guide plate **52** is rotated. In some embodiments, the cables **56**, **58** may be a single cable wound around the guide plate **52**. In some embodiments, the medical device **14** is permanently secured to the body **12** of the control **10**. In other embodiments, the medical device is releasably secured to the body **12** by including cable connectors or the like that join the control cables in the medical device to the control cables in the body **12**.

Also secured to the shaft **54** at a location adjacent the control cable guide plate **52** is a stop plate **70**. The stop plate **70** has a raised lip **72** with a pair of holes **74**, **76** therein through which the control cables **56**, **58** are passed. Each of the control cables **56**, **58** are preferably bowden cables, whereby the holes **74**, **76** are sized such that the inner control cable of the bowden-type cables passes through the holes but the outer sheaths **56***a*, **56***b* of the bowden cables are too large to fit through the holes **74**, **76**. In one embodiment, the stop plate **70** is shaped so that it does not rotate in the body of the control **10** when the actuator **20** is rotated around the axis of the shaft **54**, but does move within the body of the control as the actuator **20** is tilted back and forth. The stop plate **70** allows the physician to adjust the left/right position of the medical device **14** without adjusting the up/down position or vice-versa as will be explained below.

A ball joint **80** on the shaft **54** cooperates with a corresponding socket (not shown) in the interior of the body **12** of the control **10**. A collar **82** extends between the ball joint **80** and the cap **50** whereby the shaft **54** can rotate within the collar **82**. A top plate **84** is secured to the other end of the collar **82** and has a hole through which the shaft **54** is passed. The top plate secures the proximal ends of a pair of control cables **90**, **92** that control the up/down movement of the medical device. The ball joint **80** allows the actuator **20** to be tilted back and forth with the interior of the body **12**. Movement of the cap **50** towards the proximal end of the control **10** causes the control cable **90** to tighten, thereby causing the distal end of the medical device to move upwards. Pushing the cap **50** in the direction of the distal end of the control **10** causes the control cable **92** to tighten thereby causing the distal end of the medical device to move downwards.

Movement of the actuator **20** forwards and backwards about the axis of the ball joint **80** does not cause the distal tip of the medical device to move in the left/right direction. Similarly, rotation of the cap **50** about the longitudinal axis of the shaft **54** does not cause movement of the distal tip in the up/down direction. Therefore, the orientation of the medical device can be independently controlled in the up/down or right/left directions.

In some instances the control cables may be difficult to move with manual power alone. Therefore the actuator **20** may include a power assist mechanism to aid in tensioning the control cables. Such power assist may include hydraulic or pneumatic actuators, electric motors, magnets etc. that provide the additional force required to orient the distal tip of the medical device **14** in the desired direction.

FIGS. **3**A and **3**B illustrate how movement of the distal tip of the medical device **14** in the left/right direction is decoupled from movement of the medical device in the up/down direction. In the embodiment shown, the control cables **56**, **58** controlling the left/right movement of the medical device **14** pass through the stop plate **70**. Positioned over the control cables are the outer sheaths **56***a*, **58***a* of the bowden cables (see FIG. **2**). The distal ends of the outer sheaths **56***a*, **58***a* are fixed with respect to the distal end of the medical device **14**. The proximal ends of the outer sheaths **56***a*, **58***a* are joined to the stop plate **70** and move with the cable guide plate **52**, as it is moved back and forth within the body **12**. For example, control cable **56** has an outer sheath **56***a* having one end secured to the stop plate **70** and another end abutting the internal wall of the body **12**, as shown in FIG. **3**A. The outer sheath **56***a* is looped to have enough slack such that as the actuator **20** is tilted or moved, the slack in the outer sheath **56***a* is adjusted. As will be appreciated by those skilled in the art, the amount of bend imparted by the control cables **56**, **58** to the distal tip of a medical device **14** depends upon the position of the ends of the control cables **56**, **58** with respect to a proximal end of the outer sheaths **56***a*, **58***a* of the bowden cables. Because the outer sheaths include a loop or slack that allows them to move as the actuator **20** is moved, this distance does not change as the actuator **20** is tilted forward and back in the body **12**. Therefore, a user can adjust the up/down direction of the medical device **14** by tilting the actuator **20** forwards and backwards, as indicated in FIG. **3**A and FIG. **3**B, while not changing the orientation of the distal tip medical device in the left/right direction. In some cases, it may be desirable to limit the movement of the looped bowden cables to prevent them from becoming pinched. Therefore, the body **12** of the controller may include a slot or other restraint to limit the movement of the outer sheaths of the control cables.

Although the presently disclosed embodiment of the control operates the left/right direction by rotating the cap **50** around the axis of the shaft **54**, it will be appreciated that the control cables could be arranged such that rotation of the cap causes the tip to move in the up/down direction and movement of the actuator **20** back and forth causes movement in the left/right direction. Alternatively, the actuator **20** could include nested, rotatable knobs to control both the up/down and left/right directions in a manner similar to that found in conventional endoscopes. If desired, the position of the medical device in the left/right direction can be fixed with brakes, mechanical stops, or a sufficient friction force on the cap **50** so that once the desired left/right position of the medical device is determined, the position of the medical device can remain fixed if the user releases the actuator. Alternatively, a braking force can be applied to the medical device control cables in order to fix the position of the medical device. Similarly, the position of the medical device in the up/down direction can be fixed by inhibiting movement of the actuator in the forward and aft directions, or by applying a braking force to the control cables.

FIG. **4** illustrates how a pair of controls **100**, **102** can be secured at a fixed position with respect to a patient such as on a patient table **104** in order to allow a physician to control the orientation of a pair of medical devices. The medical devices preferably include one or more integrated instruments such as biopsy forceps, cauterizers, snares, scalpels, scissors, graspers, needle holders, staplers, fiber optic or solid state imagers etc. contained therein. Alternatively, the medical devices may be catheters that include or more lumens through which instruments can be routed. A moveable gooseneck **106** allows the position of the controls **100**, **102** to be changed. Although the rails of the controls **100**, **102** are shown connected to the gooseneck **106** with a pair of bases, it will be appreciated that the rails may be connected directly to a gooseneck or table **104**, if desired. In yet another embodiment, one or more of the controls **100**, **102** may be secured to the patient such as by strapping the controls to the patient's leg, torso, head etc. In other embodiments, the controls may be secured to the operator's body or to an endoscope or guide tube that is used in the patient.

FIG. **5** illustrates how a physician **110** can use two hands to manipulate the pair of controls **100**, **102** in order to perform a procedure within a patient **115**. In practice, the medical devices controlled by the controls **100**, **102** are often used in conjunction with a visualization device such as an endoscope **120** that produces images on a monitor **122** so that the physician can view the procedure. The present invention allows a physician to use two hands to control two medical devices in order to perform examinations or surgical procedures in the GI tract, colon, lungs, or through another orifice of the patient. Alternatively, the medical devices can be inserted through an incision such as with a trocar to access other areas of the body.

FIGS. **6**A-**6**E illustrate another embodiment of a control system for selectively orienting a medical device in accordance with the present invention. In this embodiment, a control **140** is slidably connected to a rail **142** with a pair of clamps **148** and **150**. The clamps allow the actuator **140** to move lengthwise along the rail **142**. In one embodiment, the clamps **148** and **150** allow the control **140** to be rotated about the longitudinal axis of the rail **142**. The control **140** includes an actuator handle **160** that allows a user to control the orientation of a distal tip of a medical device **250** as will be explained below. The handle further includes a trigger **164** that allows a user to actuate a tool within the medical device **250**.

FIG. **6**B illustrates further details of a control **140** in accordance with an embodiment of the present invention. The control **140** is coupled to the rail with one or more U-shaped clamps **148** and **150**. Each of the U-shaped clamps includes a pair of spaced-apart arms **152** that are connected to a pair of side rails **156***a*, **156***b* that extend for the length of the control and form a frame to which additional components of the control can be secured. The arms of the clamps **148**, **150** are secured to the side rails **156***a*, **156***b* with a fastener such as a rivet, screw, adhesive, or the like. The actuator handle **160** is rotatably coupled to the side rails **156***a*, **156***b* such that the handle is able to move forward and aft within the control **140**. In addition, the handle **160** can rotate about a longitudinal axis of a shaft **166**. Movement of the handle back and forth causes the distal tip of the medical device **250** to move in one plane while rotation of the actuator handle **160** about the longitudinal axis of the shaft **166** causes movement of the distal tip of the medical device **250** in another plane.

FIG. **6**C illustrates further detail of the actuator handle **160**. As indicated above, the handle is secured to the pair of side rails **156***a*, **156***b* with a trunnion **170** shown in FIG. **6**B. A trunnion **170** includes a pair of outwardly extending posts **172**, **174** that fit in corresponding holes formed in the side rails **156***a*, **156***b*. A locking mechanism such as a snap ring or other fastener secures the posts **172**, **174** into the side rails. The handle **160** is rotatably secured to the trunnion **170** with a shaft **166**. A collar **168** fits over the shaft between the trunnion **170** and the handle **160**. The collar **168** provides a stop for a bowden-type cable as will be described in further detail below. The trunnion **170** further includes a stop plate **176** that provides an anchor for the ends of the bowden-type cables in the same manner as the stop plate **70** shown in FIG. **2**. The stop plate **176** pivots back and forth with the posts **172**, **174** as the handle **160** is moved back and forth in the control. The trunnion **170** further includes a slot in the center of the trunnion and between the posts **172**, **174** in which a cable guide plate or disk **180** is located. In this embodiment, the cable guide plate **180** is generally circular and includes a groove **182** therein in which an actuating cable **184** is fitted. The cable guide plate **180** includes a notch **184** that receives a corresponding cable stop **186** that is secured to the cable **184**. The cable is wrapped around the cable guide plate **180** and includes a pair of legs that are coupled directly and indirectly to the distal end of the medical device. Movement of the cable guide plate causes corresponding tension or relaxing of the legs of the cable **184**. The cable guide **180** is fitted into a slot within the trunnion such that it lies behind the stop plate **176**. The shaft **166** fits through a corresponding hole in the cable guide plate **180** and a snap ring or other fastening mechanism secures the components together. Rotation of the handle **160** causes a corresponding rotation of the shaft **166** which in turn is coupled to the cable guide plate **180** to tension or release the legs of the actuating cable **184**.

FIG. **6**D illustrates further detail of the trunnion **170** within the control **140**. The cable guide plate **180** is fitted within the slot of the trunnion **170** and rotates back and forth within the slot by rotation of the actuator handle **160**. To limit the amount of forward and aft movement of the handle **160** in the control, a ring **207** that fits over the posts of the trunnion **170** has a notch **205** therein. A pin **203** secured in the side rail (not shown) limits how far the handle can travel by engaging the ends of the notch **205**.

Also shown in FIG. **6**D is a cable **190** that is actuated by the trigger mechanism **164** on the handle. Depressing the trigger **164** causes a tensioning of the cable **190** to actuate a tool within the medical device. In the embodiment of the invention illustrated, the cable **190** is a bowden-type cable having an outer sheath **192** with one end secured to a cable stop **196** positioned on the collar **168** that is fitted over the shaft **166**. The other end of the bowden cable joins a stop **198** that is fitted within a crossbar **200** extending between the pair of side rails **156***a*, **156***b*.

The crossbar **200** also includes stops for the bowden-type cables that are driven by rotation of the handle as described above.

As shown in FIG. **6**D, the trunnion also includes a shaft that extends in a direction perpendicular to the posts that are coupled to the side rails. The shaft includes a pair of cable receivers **202**, **204** having a slot or other receptacle therein that secures an end of an actuation cable. One of the cable receivers **204** is below the pivot point of the trunnion **170**, and the other is above the pivot point. Upon tilting the trunnion **170** in the control **140**, the cable receivers **202**, **204** selectively tension or release control cables that move the distal tip of the medical instrument **250** in a plane.

Further detail of one embodiment of a trigger mechanism **164** is shown in FIG. **6**E. In this embodiment, the trigger **164** is rotatably received within the handle **160** such that squeezing the trigger **165** causes it to rotate about a pivot point. The trigger **160** includes an outwardly extending arm **165** to which an end of the actuation cable **190** is secured. As the arm is moved by pressing the trigger, tension on the control cable **190** is increased to actuate the tool at the end of the medical device. A roller or pulley **167** changes the direction of the control cable **190** from within the handle to a direction that extends along the shaft **166**.

FIG. **6**F illustrates one embodiment of a coupling mechanism that can be used to selectively couple the control **140** to one or more control wires within the medical device **250**. The coupler **220** forms an end-wall that is positioned within the actuator housing **140** between the support rails **156***a*, **156***b*. The coupler **220** has a number of spring loaded pins **222***a*, **222***b*, **222***c*, etc., positioned therethrough. Each of the pins **222***a*, **222***b*, **222***c*, etc., is connected to a control cable that is moved by the handle **160** or the trigger mechanism **164** as described above. Each pin includes a cable receiving notch **224** therein that receives the ball or stop at the end of a corresponding control cable **226***a*, **226***b*, **226***c*, etc. for the medical device. Secured by a cable ball in the slots **224**, each pin allows the tensioning or release of the corresponding cables **226***a*, **226***b*, **226***c*, etc. In the embodiment shown, each of the pins **222***a*, **222***b*, **222***c*, etc. includes a spring **228***a*, **228***b*, **228***c* that biases the pin toward the distal end of the control **140**. The springs **228** serve to tension the control cables within the body of the control when not being pulled by the actuator.

To connect a medical device **250** to the control **140**, the ball ends of each of the control cables **226***a*, **226***b*, **226***c*, etc. are inserted into each of the cable receiving slots **224** of the corresponding pins. Similarly, to disconnect the cable, the balls or cable ends are removed from the cable receiving slots **224**. Upon completion of a procedure, the medical device **250** can be uncoupled from the control **140**, cleaned or sterilized for re-use or thrown away.

FIGS. **7**A-**7**I illustrate a number of alternative trigger mechanisms that allow a tool to be actuated from the control that orients a medical device in the up/down, right/left, forward/backward, and rotational directions.

FIG. **7**A illustrates one embodiment of a trigger mechanism for use with an actuator **300**. In this embodiment, the actuator **300** controls the orientation of a shaft **302** of a steerable medical device in the manner described above. The shaft **302** includes a tool such as biopsy forceps **304** that is operated by selectively tensioning or releasing a control wire **306**. In this embodiment, the trigger mechanism includes a thumb wheel **310** about which the control wire **306** is wound. Movement of the thumb wheel **310** about an axle winds or unwinds the control wire **306** on the thumb wheel, thereby tensioning or releasing the control wire coupled to the jaws of the biopsy forceps **304**.

FIG. **7**B illustrates another embodiment of a trigger mechanism for activating a tool such as a biopsy forceps **304** at the distal end of a steerable medical device. In this embodiment, a control wire **306** is connected to a pull ring **320** at one end and to the tool at the other end. Selective tensioning and releasing of the pull ring **320** tightens or releases the control wire **306**. In some embodiments, the control wire **306** or the pull ring **320** may be spring biased to return the control wire to either the tensioned or untensioned state.

FIG. **7**C illustrates another embodiment of a trigger mechanism for operating a tool such as a biopsy forceps **304** at the distal end of a steerable medical device. In this embodiment, a slider **330** is coupled to the control wire **306** that operates the biopsy forceps **304**. The slider **330** is movable within a slot **332** on the control. Movement of the slider **330** in the proximal direction tensions the control wire **306**. Similarly, movement of the slider **330** in a distal direction selectively releases the control wire **306** to activate the tool.

FIG. **7**D illustrates yet another embodiment of a trigger mechanism for operating a tool such as a biopsy forceps **304** at the distal end of a steerable medical device. In this embodiment, a control wire **306** that operates the biopsy forceps **304** is connected to a switch type mechanism **340**. Movement of the switch about a pivot point **342** causes the control wire **306** to be wound or unwound around a spool **346** that is coupled to the switch **340**. With the control wire **306** wound around the spool **346**, tension on the control wire is increased, while unwinding the control wire **306** from the spool **346** causes the tension to be released in order to operate the biopsy forceps **304**.

FIG. **7**E illustrates yet another alternative embodiment of a trigger mechanism for controlling a biopsy forceps **304** at the distal end of a steerable medical device. In this embodiment, a trigger mechanism includes a push button **360**. The push button **360** is preferably biased with a spring **362** that causes the button to return to a predefined state. Coupled to the push button **360** is a shaft **364** including an angled slot **366** therein. A post **368** connected to the drive cable **306** moves within a slot **370** that is longitudinally aligned with the actuator and in the angled slot **366**. The angled slot **366** on the shaft **364** moves the post **368** back and forth within the slot **370** as the push button **360** is moved up and down in order to actuate the biopsy forceps **304**.

In some embodiments, the push button may be located on the handle of the actuator. As shown in FIG. **7**F, a button **390** actuates a cable **306**, where the cable includes an outer bowden cable sheath **392** positioned between the actuator and a fixed position **396**, for example, within the actuator (not shown). Pushing the button **390** tightens or releases the cable **306** that controls the tool that is actuated with the cable **306**.

FIG. **7**G shows yet another embodiment of a trigger mechanism for actuating a tool such as a biopsy forceps from a control. In this embodiment, the handle **400** of the control includes a V-shaped groove **420** that separates portions of the handle. The handle **400** is flexible so that the V-shaped groove can be collapsed or expanded. A control cable **306** is split in a Y-type configuration wherein each leg of the Y is contained in a different side of the V-shaped groove in the handle. Compression of the handle **400** about the V-shaped groove **420** causes the end points of the cable **424**, **426** to move toward one another, thereby lengthening the cable. Upon expansion of the V-shaped groove, the end points **424**, **426** of the control cable **306** are spread apart, thereby shortening the cable and actuating a tool. The handle **400** may be made of a plastic material that allows it to bend. Alternatively, the handle may include a hinge mechanism to allow it to bend.

FIG. **7**H shows yet another alternative embodiment of the trigger mechanism for actuating a cable **306** connected to a biopsy forceps **304** or other tool at the distal end of a steerable medical device. In this embodiment, a handle **450** is spring loaded so that it can be pressed downwards. A control cable **306** has an end coupled to the handle such that pressing the handle releases tension on the control cable. Releasing the handle increases tension on the control cable **306** to actuate the biopsy forceps.

FIG. 7I illustrates yet another embodiment of trigger mechanism **460** that actuates a tool **304** such as a biopsy forceps with a control wire. In this embodiment, the trigger mechanism is a pneumatic, hydraulic or electromagnetic actuator such as a solenoid, linear motor, etc. that is activated by a switch **462** such as a foot switch. Activation of the trigger selectively tensions or releases a control cable **306** that actuates the tool **304**.

Although the described embodiments actuate a tool at the distal end of a steerable medical device, it will be appreciated that the tool may be positioned at other locations on the steerable device.

While embodiments of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the scope of the invention. For example, additional actuator(s) could be included in the controls to tension/release control cables that terminate at other locations along the length of the medical device. For example, control cables may be secured to a location more proximal than the distal tip in order to provide bending at a more proximal portion of the device. These control cables can be tensioned with a second actuator on the control body. Alternatively, a single actuator can be used to tension more than one set of control cables. The actuator can selectively engage mechanisms to tension different control cables. Brakes or other devices can be used to fix the position of one set of control cables while the control cables from another set are adjusted. With a set of distal control cables and a set of proximal control cables, a tool in the medical device can have up to seven degrees of freedom (up/down, left/right at the distal end, up/down, left/right proximally, forward/backward, rotation about its axis and movement of the tool).

In some embodiments, movement of a medical device in the up/down, left/right direction may be controlled with actuators such as servo motors, hydraulic, pneumatic actuators disposed in a housing that is movable along and rotatable over a fixed rail in order to adjust the distal/proximal movement of a medical device as well as rotation of a device.

In another embodiment, instead of using clamps to secure the control to a rail, the control **10** can be placed in a cradle **17** to allow the control **10** to be rotated about its own longitudinal axis. Alternatively, the clamps that hold the control can be designed with slidable connections or the like to allow the control to rotate about its longitudinal axis. If allowed to rotate, there may be less translation error compared with the embodiments of the invention wherein the control is rotated about the rail that control the longitudinal distal and proximal movement of the medical device.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A control for selectively orienting a medical device of the type having control cables configured to actuate a distal tip of the medical device in one or more of an up/down direction and a left/right direction, comprising:

- a body;
- an actuator coupled to the body, wherein the actuator is configured to move independently in at least two directions relative to the body;
- a first pair of control cables mechanically coupled to the actuator and configured to move when the actuator is moved in a first direction;
- a second pair of control cables mechanically coupled to the actuator and configured to move when the actuator is moved in a second direction;
- wherein at least one of the first or second pair of control cables has an inner cable and an outer sheath arranged such that one end of the inner cable and outer sheath move with respect to one another when the actuator is moved in one of said two directions and do not move with respect to each other when the actuator is moved in the other of said at least two directions; and
- a trigger configured to actuate an instrument located at the distal tip of the medical device for performing a procedure on a patient, wherein the trigger is located on the actuator.

2. The control of claim **1**, further comprising:

- a rail mounted to a fixed surface with respect to a patient along which the control is moveable to advance or retract the medical device.

3. The control of claim **2**, further comprising at least one clamp configured to permit rotation of the body about a longitudinal axis of the rail.

4. The control system of claim **2**, further comprising a cradle configured to receive the control, wherein the cradle is configured to permit rotation of the body about a longitudinal axis of the rail.

5. The control of claim **1**, wherein the trigger actuates a trigger cable having an inner cable configured to move relative to an outer sheath.

6. The control of claim **1**, wherein the trigger actuates a trigger cable that includes a coupler for attachment to a corresponding trigger cable at least partially located within the instrument.

7. The control of claim **6**, wherein the coupler includes a spring loaded pin having a receiving notch configured to receive an end of the corresponding trigger cable.

8. The control of claim **1**, wherein at least one of the first pair of control cables and the second pair of control cables are located within the body.

9. The control of claim **1**, wherein the medical device includes a catheter having a lumen configured to receive the instrument.

10. The control of claim **1**, wherein at least one of the first or second pair of control cables includes a coupler for attachment to a corresponding control cable.

11. A method of performing a minimally invasive procedure on a patient with a medical device having a distal tip by:

- delivering the distal tip of the medical device to an internal location within the patient; and
- selectively controlling the orientation of the distal tip of the medical device with a proximally located control that comprises:
  - a body;
  - an actuator coupled to the body, wherein the actuator is configured to move independently in at least two directions relative to the body;
  - a first control cable mechanically coupled to the actuator and configured to move when the actuator is moved in a first direction;
  - a second control cable mechanically coupled to the actuator and configured to move when the actuator is moved in a second direction; and
  - a trigger moveably coupled to the actuator;
- selectively moving the actuator in the first direction to move the distal tip of the medical device in an up/down direction;
- selectively moving the actuator in the second direction to move the distal tip of the medical device in a left/right direction, wherein movement in the up/down direction is decoupled from movement in the left/right direction; and
- moving the trigger relative to the actuator to actuate an instrument located at the distal tip of the medical device.

12. The method of claim **11**, further including moving a distal end of the instrument longitudinally relative to the distal tip of the medical device.

13. The method of claim **11**, further including decoupling the control from the medical device.

14. A control system for selectively orienting a medical device, comprising:
- a rigid rail having a longitudinal axis;
- a clamp configured to move along the longitudinal axis of the rail;
- a control fixedly secured to the clamp, wherein the control is configured to move along the longitudinal axis of the rail, the control including:
  - a body;
  - an actuator including a handle coupled to a shaft having a longitudinal axis, wherein the shaft is pivotally coupled to the body to permit tilting of the handle with respect to the body, and the shaft is rotationally coupled to the body to permit rotation about the longitudinal axis of the shaft with respect to the body;
  - wherein the shaft is mechanically coupled to at least two pairs of control cables that are moveable to control the orientation of a distal end of the medical device such that tilting of the handle causes the distal end of the medical device to move in a first plane and rotation of the handle causes the distal end of the medical device to move in a second plane that is different to the first plane; and

  - a trigger moveably coupled to the actuator and configured to actuate an instrument located at the distal end of the medical device.

15. The control system of claim **14**, wherein the shaft is coupled to the body with a trunnion.

16. The control system of claim **15**, wherein the shaft is coupled to a cable stop that moves with the shaft and the at least two pairs of control cables include two or more bowden cables coupled to the cable stop.

17. The control system of claim **14**, wherein the trigger is located on the handle.

18. The control system of claim **17**, wherein the handle is manipulatable by a hand of a user and the trigger is separately manipulatable by a digit of the hand.

19. The control system of claim **14**, wherein the handle is elongate and has an elongate axis and the shaft has a first end and a longitudinal axis, further wherein the longitudinal axis of the shaft is positioned generally perpendicular to the elongate axis of the handle, and the first end of the shaft is connected to the handle.

20. The control system of claim **19**, wherein the body has a longitudinal axis, and the longitudinal axis of the body is positioned generally perpendicular to the longitudinal axis of the shaft.

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